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Part II

Department of Agriculture

Food Safety and Quality Service

Department of Health and Human Services

Food and Drug Administration

Net Weight Labeling

DEPARTMENT OF AGRICULTURE

Food Safety and Quality Service

9 CFR Parts 317 and 381

Net Weight Labeling

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposal would amend the Federal meat and poultry products inspection regulations to provide more uniform labeling requirements and to prescribe uniform procedures for determining compliance with label statements of net contents of containers of meat and poultry products. The proposal would establish objective, numerical variations from the labeled net weight which are to be determined by prescribed procedures. This proposal is designed to enhance the ability of Federal, State and local agencies to enforce strict net weight standards at the retail level and would establish greater uniformity with regulations for net weight compliance used by the Food and Drug Administration for other types of foods.

DATE: Comments must be received on or before November 6, 1980.

ADDRESSES: Written comments to: Regulations Coordination Division, Attn: Annie Johnson, Room 2637, South Agriculture Building, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250. Oral comments on the poultry products inspection regulations to: Mr. Bill F. Dennis, (202) 447–3840.

FOR FURTHER INFORMATION CONTACT: Mr. Bill F. Dennis, Director, Processed Products Inspection Division, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447–3840. the Draft Impact Analysis detailing the options considered in developing this proposed rule and the impact of implementing each option is published in its entirety below as an appendix to this proposal.

SUPPLEMENTARY INFORMATION:

Significance

This proposed action has been reviewed under USDA procedures established in Secretary's Memorandum 1955 to Implement Executive Order 12044, and has been classified "significant."

Comments

Interested persons are invited to submit comments concerning this proposal. Written comments must be sent in duplicate to the Regulations Coordination Division and should bear a reference to the date and page number of this issue of the **Federal Register.** Any person desiring opportunity for oral presentation of views on the poultry product inspection regulations must make such request to Mr. Dennis so that arrangements may be made for such views to be presented. A transcript shall be made of all views orally presented on the poultry product inspection regulations. All comments submitted pursuant to this notice will be made available for public inspection in the office of the Regulations Coordination Division during regular hours of business. For more information about how to participate in this proceeding, contact the FSQS Public Participation Office at (202) 447–7804.

The Proposal

The Department of Agriculture (USDA) is proposing regulations setting forth more uniform net weight labeling requirements for federally inspected meat and poultry products and prescribing procedures for determining compliance with these requirements. These proposed regulations would establish objective, numerical standards for determining compliance to insure that consumers receive valid information regarding the actual weight of meat and poultry products and to provide for increased iniformity of regulation at the Federal, State and local levels.

Under the Federal Meat Inspection Act (21 U.S.C 601 *et seq.*) and the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), the Department must assure that meat and poultry products sold and distributed in commerce are properly labeled and are not misbranded in any way. The Acts require an accurate statement of net quantity of contents, but allow the Secretary to establish reasonable variations by regulation (21 U.S.C. 451(h)(5), 601(n)(5)).

The Department's current net weight regulations for meat products (9 CFR 317.2(h)) and poultry products (9 CFR 381.121) state that the labeled net weight shall not be false or misleading and shall express an accurate statement of the quantity of contents, exclusive of wrapping and packing substances. The regulations allow for reasonable variation from the labeled net weight caused by (1) moisture loss or gain during the course of good distribution practices or (2) unavoidable deviations during good manufacturing practices.

While Department studies show substantial compliance with these regulations, consumers and State law enforcement officials have voiced concerns with their application. Some consumers say that product labels may not be supplying accurate information about the product being purchased. The permitted variations attributable to moisture loss cause some consumers to believe that they may be paying too much for a meat or poultry product. State enforcement personnel indicate that they believe they are unable to protect consumers adequately because of the lack of objective, numerical procedures and standards for determining the allowable variations. As one commenter suggested on behalf of a State Department of Agriculture regarding a recent Department study of the net weight issue, the permitted variations in the present USDA regulations ". . . confound the attempts of any inspection agency to determine if quantity labeling is correct when inspection takes place at any point in the distribution chain. Further, such condition leads to the inability of a prospective purchaser to successfully accomplish value comparison, based on quantity and between commodities." [1]

The Department proposes to amend its current net weight regulations by:

1. Replacing the currently permitted "reasonable variations" due to loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practices with allowable numerical variations which appear to be reasonable when determined by specified procedures. The allowable variations are based on recognized, unavoidable deviations which occur during the manufacturing process. Allowance for moisture loss was not made in development of these variations. Proposed allowable variations were determined after extensive consultation with the National Bureau of Standards. These variations would be used and enforced at the time of production, during distribution, and at retail sale by Federal, State, and local regulatory officials within their respective regulatory authorities.

2. Establishing a definition of "tare" [2] in which the net weight of a product

[1] Comments submitted by the Maryland Department of Agriculture in a letter dated October 26, 1979, in response to a request for comments on the results of the ESCS study published in the **Federal Register** on August 31, 1979 (44 FR 51275–51277).

[2] "Tare" is the term used to refer to the weight of those parts of the gross weight of a packaged product not included in the labeled net weight. Typically, tare includes the weight of packaging materials or container of a product.

equals the package and contents minus the weight of the packaging materials. With regard to liquids absorbed by the packaging material, the Department has developed two alternatives as to whether or not such liquids should be included in net weight. Under the proposed regulations, too, free liquid (liquid which has separated itself from the product but which has not been absorbed by the packaging material) is included in the net weight of the product, except for those few products which are packed in substances which are normally discarded before consumer preparation and/or serving.

3. Establishing specific sampling procedures to assure consistent weight measurements and compliance determinations by Federal, State and local regulatory personnel. Under the procedures, while an allowable variation may be permitted for individual packages, the net weight of all the sample packages must meet or exceed the stated net weight.

4. Establishing consistent limited labeling exemptions for meat and poultry products which meet criteria for "small packages" and "multi-unit packages."

This proposed regulation would have an impact upon the Department and any federally inspected meat and poultry establishment packaging products affected by the proposed changes. State and local agencies responsible for enforcement of net weight labeling rules, any wholesale and retail establishments subject to the rules applying to meat and poultry products, and consumers.

Purpose and Need for Action: A revised regulation would serve several purposes. It would:

1. Create standards that will be easily enforceable so that the net weight statement is as accurate as can reasonably be required at the time meat and poultry products are purchased by consumers.

2. Enable State and local regulatory agencies to enforce strict net weight standards at retail and other locations within their jurisdictions where meat and poultry products are sold.

3. Establish net weight regulations that are generally uniform with those used by the Food and Drug Administration (FDA) for other food products.

Background

The need for this proposal is based on three developments, the first of which occurred in 1972.

1. *Rath v. Becker.* In the course of developing weights and measures regulations over the years, some State and local governments did not provide for any "reasonable variation" in net weight caused by moisture loss or gain during the course of good distribution practices, as is provided under the Department's regulations pursuant to Federal law. California was one of these States. In 1972, a local official in California ordered "off-sale" a federally inspected meat product with a net weight below the declared net weight as determined by the State procedure. The food product's manufacturer sought relief in Federal district court.

The manufacturer alleged that its product was in compliance with the Federal requirements at the time of Federal Inspection and that California could not impose additional or different State requirements. In this case, *Rath Packing Company v. Becker,* 357 F. Supp. 529 (C.D. Cal. 1973), the United States District Court for the Central District of California in 1973 held that the Federal Meat Inspection Act (FMIA) pre-empts State and local governments from imposing net weight labeling requirements on federally inspected meat products that are in addition to or different from the Federal requirements. Furthermore, the misbranding and mislabeling provisions of the FMIA were held to apply not only at the official establishment packing the product, but at all levels in the distribution chain including retail. The court held, however, that the Federal regulation allowing "reasonable variations" with respect to net weight (9 CFR 317.2(h)(2)) was void to vagueness.

This decision was appealed to the United States Court of Appeals for the Ninth Circuit. In October 1975, this Court affirmed the decision on pre-emption, but reversed the decision that the "reasonable variations" regulation (9 CFR 317.2(h)(2)) was void due to vagueness (530 F.2d 1295 (9th Cir. 1975)).

The decision on the pre-emption issue was further appealed to the U.S. Supreme Court, where it was affirmed in March of 1977. (*Jones* v. *Rath Packing Company,* 430 U.S. 519 (1977)).

2. *The 1973 Proposal.* The Department believed it was a practical necessity to allow reasonable variations from the declared net weight. Therefore, after the District Court voided the existing "reasonable variations" regulation, the Department proposed a new regulation on December 3, 1973 (38 FR 33308–33313). Procedures were proposed for determining allowable net weight variations at the producing plant and during distribution. With explicit numerical allowed net weight variations, packers would have needed to target the fill weight above the stated contents to assure compliance. Recoverable liquids that drained from the product would have been considered as part of the net weight. For compliance purposes, each federally inspected establishment packing containers for sale to household consumers would have had to implement an approved quality control program, in accordance with specific recommendations contained in the proposal.[3] In addition, existing provisions exempting shingle packed sliced bacon from various general net weight labeling requirements would have been eliminated.

Public hearings held during 1974 in five locations (New York City, Washington, D.C., Atlanta, Dallas, and San Francisco) to explain this proposal revealed widespread dissatisfaction on the part of consumers, industry representatives, and State and local weights and measures officials. Over 1,600 comments on the proposal were recorded. Twenty-one consumer groups responded. Eight of these groups objected to paying for water, blood, and packing media, and wanted the label to bear the actual net weight of the product. Six expressed the opinion that there is no effective way to prevent the sale of short weight products. A total of 69 industry groups responded, 33 of which wanted controls directed only to the marked consumer-size packages. Twenty others believed the limits to be "too tight," and 16 believed the industry would have to resort to vacuum packaging to comply. Over 1,300 individuals submitted comments of which 70 percent wanted labels to contain an accurate net weight statement, 25 percent objected to paying for fluid and packing media as part of the net weight, and the remainder objected to Federal pre-emption of State and local rules. In essence, no group expressed unqualified support for the proposal.

3. *The 1977 Proposal.* The third development occurred following the U.S. Supreme Court decision in 1977 which upheld Federal pre-emption. California and 47 other States, the District of Columbia and American Samoa acting as cosigners petitioned the Department, the Food and Drug Administration (FDA) and the Federal Trade Commission to amend the existing Federal regulations (9 CFR 317.2(h)(2), 9 CFR 381.121(c)(6), 21 CFR 101.105(q), 21 CFR 501.105(q) and 16 CFR 500.22) to create a more enforceable net weight regulation.

The petitioners and supporters claimed that the Federal net weight

[3] Currently and at the time of the 1973 proposal, at official establishments where retail products bearing net weight labels are packaged, USDA inspectors periodically weigh lots of product for net weight compliance.

labeling regulations are unfair to consumers who do not receive the full measure as represented on the package and that these regulations create a situation that precludes enforcement by State and local officials at the retail level because the phrase "reasonable variations" is undefined and vagued. The petitioners proposed to require a minimum declared weight, suggesting either overfilling to compensate for moisture loss or improving the food packaging to impede moisture loss to insure the minimum weight of food at any point during distribution. The petitioners contended that industry has the capability to evaluate all the variables affecting moisture loss for their products and can, therefore, adjust the processing and target weights accordingly to minimize excessive overfilling.

In response to the petitions, consumer complaints, and comments received concerning the 1973 proposal, the Department published a new net weight labeling proposal in the **Federal Register** on December 2, 1977 (42 FR 61279–61284). The intent of the proposal was to provide consumers with labeling information based upon the *usable* weight of the meat and poultry contents of the package at the time of purchase. To accomplish this, it proposed several changes:

a. *Adopt weight definitions.* The 1977 proposal would have defined the new weight as the gross weight of the unopened container minus the tare weight. The tare weight was to be the gross weight of the unopened container minus the drained weight of the product therein. To determine the drained weight, the package would be opened and the contents allowed to drain for 2 minutes on a specified size mesh screen. By the use of these definitions and procedures, the new weight statement on the container would not include all of the drainable liquids in the container.

b. *Adopt a new definition of reasonable variation.* Currently, reasonable variations are allowed for unavoidable deviations in good manufacturing practice and for loss or gain of moisture during the course of good distribution practices. The proposal would have eliminated this allowance. In its place, the proposed rule would have established numerical variations to be determined by prescribed procedures, including defined sampling plans. The average net weight of the samples was required to equal or exceed the stated net weight. An individual sample was to be allowed a specified numercial deviation below the stated net weight. Homogeneous products that are fluid when filled would have been allowed less variation than heterogenous products which are not as easily packaged.

C. *Adopt a mandatory net weight quality control program.* A net weight quality control program, approved and monitored by USDA, would have been required for establishments under Federal inspection for immediate containers bearing net weight labels (see footnote 3).

d. *Adopt a tightened inspection sampling procedure.* Under current in-plant practices, if 40 or more sample packages are taken from a lot, one of those packages can have an unreasonably large deviation from the labeled weight, as long as the average net weight of all of the sample packages equals or exceeds the labeled net weight. Under the 1977 proposal, the entire lot would be out of compliance if any sample package had a deviation from its labeled net weight larger than the numercial amount specified in the proposal.

e. *Bulk shipments would continue to be covered by the regulation.* The proposal would have required a net weight statement on the labels on the immediate (shipping) containers of bulk shipments, and shipping containers of small packages after the product is shipped from the plant. The 1973 proposal had proposed to provide manufacturers and packers broad leeway in the bulk package net contents statement.

Comments on the 1977 Proposal

Over 3,000 comments were received on this proposal, many questioning its need and contending that it would raise prices. It had been recognized that the proposal would be controversial for several reasons. First, since the net weight would not include all of the drainable liquids, the compliance procedures would require the opening and repackaging of contents and a possible loss of product during distribution and before final sale—a far more expensive technique for industry and more time consuming for Federal and State regulators than checking for compliance by weighing the entire package and subtracting the weight of the dry packaging material before the product is packaged (the "dry tare"). Second, in order to achieve compliance, product packagers would have to develop estimates of possible shrink and liquid loss in net weight between the times of packaging and final sale to consumers and compensate accordingly or otherwise provide assurance that the declared net weight on the package is correct throughout the rest of the distribution system by overpacking.

Over 2,700 comments came from individuals, with 71 percent of them opposed, contending it would over-regular the industry and increase foods costs. Twenty-six percent of consumers commenting supported the proposal, and the balance objected specifically to the provision to exclude the free liquid in the container from the net weight. State and local weights and measures officials were almost unanimous in supporting the proposal, with only four out of 114 objecting. The 31 industry groups were all opposed because they believed that there were no sufficient variations for bulk packed items and that it was unclear who would be responsible for short weights at retail. University groups were almost evenly split with 15 supporting the proposal, and 12 against because it would raise consumer costs. All but one of the 21 consumer groups supported the proposal. Of all the respondents, slightly over two-thirds opposed the proposal.

Events following the 1977 Proposal. As a result of the strong negative response to the 1977 proposal, the Department sought additional data on which to reconsider its proposal. These documents helped shape the present proposal:

1. *The GMA Petition.* In 1978, USDA and FDA received a petition submitted by the Grocery Manufacturers of America (GMA) on behalf of those favoring an allowance for "reasonable variations" due to moisture loss. GMA claimed that the continuation of the existing nonqualified allowances is essential. GMA maintained that no chronic short-weight problems have existed for well over a decade, thereby illustrating the enforcement effectiveness of the present regulations. In the cases where moisture loss can affect weight, GMA contended that the consumer is getting full value based on the nutritional food "solids." Industry representatives stated that moisture loss occurring during distribution and storage is beyond the control of the manufacturer. GMA maintained that the modifications proposed in the State of California petition calling for overfilling and improved food packaging would provide no consumer advantage and could result in higher food costs. Instead, GMA recommended the creation of a National Net Weight Assurance Program to (a) establish a list of foods subject to moisture loss or gain, together with a normal moisture range at time of packaging, (b) foster the determination of net weight compliance of products through periodic inspections

at the time of packaging, and (c) develop procedures for establishing a cooperative inspection program and for the exchange of enforcement data between States and the Federal Government. GMA further encouraged conducting net weight labeling inspections in accordance with statistical sampling procedures described in a draft of the revision of the National Bureau of Standards Handbook 67, dated December 1977. This petition has received widespread support from the food industry.

2. *The Consumer Federation of America Study.* In order to obtain information on the economic benefits and cost of the proposal and to resolve other allegations presented by industry and consumer groups, the Department awarded a study contract to the Consumer Federation of America. The study was completed in October 1978, but failed to reach any conclusions. It did observe that: "Consumers cannot be expected to have different interpretations of labeled net weight depending on the particular food product being sold" and that "Consumers are more hurt by shortweighing than they are benefited by overpack because of the declining marginal utility of the product."[4]

3. *The GAO Study.* In the meantime, the House Committee on Agriculture requested the General Accounting Office (GAO) to evaluate the proposed net weight regulation and consider the feasibility of alternative systems. The GAO report, issued on December 20, 1978, observed that:

"Agriculture has not gathered adequate data to determine whether the current system needs to be changed or whether the proposed system or other possible alternative systems would be more economical and practical than the current system. Various Executive orders and GAO reports stress the importance of collecting and analyzing economic and other data to help choose the least burdensome and most feasible regulatory method of achieving an objective."

The report later concluded:

"We recommend that the Secretary of Agriculture direct the Service (FSQS) to expand and extend its search for information concerning the best way to monitor net weight labeling activities for meat and poultry products. Such a search should include:

—a reevaluation of the need for change;
—a comparison of available viable alternatives, including those discussed in this report;
—a comprehensive economic impact statement for each system considered;
—a thorough and objective analysis of comments from major groups including State and local government regulatory organizations, industry, and consumers affected by such activities; and
—research to resolve the packaged meat and poultry moisture loss controversy."

USDA officials agreed to the GAO recommendation to expand and extend the search for information on the best way to regulate net weight labeling.

4. *The ESCS Study.* In January 1979, the Economics, Statistics and Cooperatives Service (ESCS), an agency of the USDA, was asked to conduct a study on behalf of USDA to evaluate the accumulated evidence and reassess the economic costs and benefits for the purpose of determining the need for, and the economic impact of, the 1977 proposal.

Generally, the ESCS study found that the economic benefits from using a drained weight requirement (i.e., excluding free liquids from the net weight) were substantially less than many consumer groups had contended, but the costs of such a requirement were also substantially less than the producer groups had suggested. More specifically, the study identified benefits accruing from a drained weight approach to determining net weight. The ESCS study concluded in this issue that a drained weight labeling regulation:

—Can guarantee that most consumers receive at least the stated weight in "consumable" product. However, drained weight labeling cannot insure accuracy of the labeled weight or the labeled price per pound in terms of what is actually in a specified package.
—Is less susceptible to abuse than a dry tare inspection.
—Provides incentives for industry to reduce the amount and variability of moisture loss of products.
—Improves the ability of consumers to make value comparisons between meat and poultry products which differ widely in moisture loss.
—Facilitates on-site enforcement by State and local weights and measures officials.

On the other hand, ESCS found that the adoption of a drained weight requirement could have the effect of increasing costs to the regulated industry, State enforcement officials, and to consumers through increased costs per pound.

ESCS observed that the information presented about the 1977 proposal had resulted in considerable misunderstanding by both consumers and producers and that, in fact, there was no economic advantage to consumers from a drained weight system. The study states:

"Consumers cannot expect the reported price per pound of a product to remain unchanged if free liquids are excluded from labeled product weights. The price per pound can be expected to increase—and to increase most for those products with relatively more free liquid. However, the cost to consumers for *usable* product would remain unchanged. Actual costs to producers would not increase because of the change in definition of tare (that is, those parts of a product whose weight is not included in the labeled net weight). The amount of drained weight meat would not be affected by a labeling rule, and processing costs per drained weight pound would be unaffected."

The ESCS study also reported the following possible cost increases resulting from the adoption of the 1977 proposal:

"Mandatory quality control would increase industry costs by $59 million to $116 million. The impact on the smaller firms would be greater than on the larger firms, many of which already have quality control systems."

"Products with the highest moisture loss would likely have larger increases in their labeled price per pound relative to products with a lower moisture loss. Consumer expenditures could shift to products with relatively lower prices following the change in regulation. The full effect of these relative price shifts on expenditures, however, would depend on consumers' preceptions and knowledge about net weight labeling, as there would be no change in the real price per drained weight pound."[5]

"Retailers not located in jurisdictions currently using some form of drained weight inspection would likely have modest additional costs from more frequent rewrapping of in-store packaged product. Retailers would also absorb the cost of opened prepack packages not purchased by inspectors or returned to the processor."

[4] Analysis of Proposed Regulations on Net Weight Labeling submitted by the Consumer Federation of America to the U.S. Department of Agriculture in accordance with Contract 53-3A94-A-01.

[5] The study also observed that consumer misunderstanding could have some long term market effects if consumers believe that the real price per pound of the products with considerable quantities of free liquid actually increased. They might shift purchases to products that have a lower per pound price. ESCS did suggest, however, the problem could be largely corrected by a nationwide education program to explain the reason for the unit price change.

"The cost of sieve and receiving pans to weights and measures officials is estimated at $421,000."

5. *Comments to the ESCS study.* The ESCS study was submitted for public comment during a 60–day period ending on October 30, 1979 (44 FR 51275–51277). In addition, FSQS mailed out approximately 300 copies of the ESCS study to the organizations and individuals who had commented on the 1977 proposal in order to solicit their response on the results of the study. Copies were also distributed to individuals and others who requested the study.

A total of 101 comments were submitted to FSQS. Again, opposition was expressed to the 1977 proposal. Of the 50 industry and trade associations responding, 48 preferred the present net weight policy. However, 15 of the 18 State and local weights and measures regulatory groups expressed support for the 1977 proposal. Only 21 individuals responded, and all but two opposed the proposal. Only one of 51 consumer groups responded. The poor response is attributed to the reported desire of some to await the comment period on a new proposal before drafting a response.

Issues

As the discussion above indicates, the development of a workable, enforceable net weight standard has proven to be a difficult and controversial task. On the basis of the information generated by the various proposals and studies, in addition to the Department's own expertise and information gathered through consultation with other Federal and State agencies, the Department now believes it is appropriate and in the public interest to publish this new proposal. The 1977 proposal is accordingly withdrawn. The following discussion is provided to clarify the Department's position on a number of issues which had to be considered in the development of the present proposal.

1. *Need for a new regulation.* State officials have urged the Department to adopt a new standard despite the lack of any recent history of poor compliance with net weight requirements. The Michigan State Department of Agriculture has indicated that perhaps the past good compliance record "is an indication of the industry's desire to comply with the requirements that cause equality in the marketplace, both for the consumer and in vying with competitors. Through the pre-emption of state regulations by the Federal Wholesome Meat Act [sic], industry has lost the effect of verifiable inspections, which was the basis of equality. There will be an erosion of equality, however, since the existing federal regulations are unenforceable without this proposed regulation." the California State Department of Agriculture has also stated that "challenges to State enforcement are increasing and its is becoming increasingly difficult to obtain successful prosecution of offenders. This deterioration cannot be allowed to continue, and it surely must under the present regulation."

On the other hand, in comments received on the 1977 proposal and on the ESCS study, the Department has been advised by various representatives of the food industry that the present regulations are fully protective of the consumer. They indicate that there has been no showing of short-weighting or of economic adulteration. Therefore, they conclude there would appear to be no benefit derived from further regulation of net weight.

The Department agrees that the current system does create enforcement problems for State and local agencies. As a result of the Supreme Court decision in *Jones v. Rath Packing Company,* holding that the Federal Meat Inspection Act prevents States from issuing net weight regulations in addition to or different from the Federal standard, many State statutes and regulations, which created numerical deviation weight testing standards, became unenforceable.

Under the Federal meat and Poultry Products Inspection Acts (21 U.S.C. 467e and 678), there is concurrent jurisdiciton for enforcement between USDA and its State and local counterparts and is essential to the functioning of the regulatory system. As a practical matter, State and local officials are usually the primary compliance force at the retail level.

However, if Federal rules are difficult to enforce at retail, the system does not function as effectively as it should. Therefore, USDA has a responsibility to provide suitable standards and procedures. Accordingly, the Department proposes the revised regulation.

2. *Type of Tare.* The choice of the proper tare[6] has proven to be one of the most difficult issues faced by the Department in the formulation of this proposal. Under this proposal, net weight would be based upon a definition of tare which includes the packaging materials. With regard to liquids absorbed by the packaging materials, the Department is making alternative proposals on whether or not to include such liquids in the tare. The proposal would, in most cases, exclude free liquids from the tare weight. Thus, such free liquids would usually be included in the labeled net weight. However, for those few products which are packed in substances that are normally discarded before consumer preparation and/or serving (such as water, curing solution, brine and vinegar), a drained weight standard would be applied. Thus, for these few products, the free liquids would be included in the tare weight and not in the labeled net weight.

In selecting this approach, the Department has rejected the general drained weight approach taken in the 1977 proposal. Under that system, free liquid was to be excluded from the product's net weight. However, following further study and evaluation, particularly with regard to findings and conclusions of the ESCS study previously discussed, the Department has determined that such a system is the more expensive system to enforce and the more difficult with which to comply, while providing no additional assurance of correct information to consumers than is available under other systems.

(a) Consumer Concerns

Some consumers have objected to a dry tare system because they believe under such a system they are paying meat and chicken prices for free liquid. However, the ESCS study points out that this consumer perception may not be accurate.

Under a drained weight system, producers would likely understate the amount of net weight on the meat or poultry package to assure compliance at all locations in the distribution chain. Consumers might perceive such understatement as a reduction in the quantity contained in the package and conclude that the price of the product per pound had increased, even though they would be getting the same usable product for the price. The ESCS study stated: "What adjustments, if any, consumers would make in their expenditures for meat and poultry would depend on their perception and understanding of the real price per pound before and after the rule change."

In addition, for products with a wide variability in moisture loss, the determination of how much to understate the weight and how much to revise the price per pound would be less exact. Therefore, the ESCS study noted

[6] "Dry tare" is the weight of the dry packaging material before the product is packaged. The ESCS study also identified three other types of tare. "Wiped dry tare" is the weight of the used packaging material that has been opened and wiped clean so that is approximates the weight of the unused material. "Wet tare" includes used packaging material plus any liquid absorbed by the material. "Drained weight tare" includes the used packaging material plus all absorbed, as well as free, liquid.

that for such products it is unlikely that drained weight labeling would better enable consumers to use net weight statements to make comparisons among different packages of a particular product.

The ESCS study provides the following explanation of the practical effects of using the drained weight system instead of the dry tare system:

"Under dry tare regulations, a package of chicken breasts selling for $1.20 per pound with a labeled weight of 3.0 lb. costs the consumer $3.60. Assuming the package suffers the average moisture loss of 4 percent, the consumer actually receives 2.88 lb. of drained weight chicken. The real price per pound of drained chicken is *$1.25* ($3.60÷ 2.88 lb.).

"With drained weight regulations, the processor will increase the tare enough to allow for a 6 percent moisture loss (2 percent above the average to assure compliance). The labeled net weight would be 2.82 lbs. To compensate, the *labeled* price will be increased from $1.20/lb. to $1.28/lb. The cost of the package will remain $3.60 (2.82/lb. X $1.28/lb.). Assuming the package suffers the average 4-percent moisture loss as above, the drained weight will be 2.88 lb. Just as before, the real price per pound of drained weight chicken is *$1.25* ($3.60÷ 2.88 lb.).

"In summary, drained weight labeling regulations can alter the information a consumer receives, but not the real cost of the product.

"Whether consumers pay chicken prices for water is not clear simply because a dry tare labeling weight is allowed. If $3.60 is the competitive cost for a 3-lb. package of chicken breasts, then the consumer is not paying $1.20/lb. for 0.12 lb. of water and juices. The consumer is simply not being informed that the true price of chicken at the retail level on a drained weight basis is $1.25/lb., not $1.20."

Thus, the Department has determined that a general drained weight system does not provide an important economic benefit to consumers.

(b) Industry Concerns

Industry also advised the Department of its problems with the drained weight system as specified in the 1977 proposal. Under that proposal, industry would have had to substantially increase the amount of overfilling, or understating of weight, on many meat and poultry products to comply with drained weight labeling. Although some industry commenters suggested it might be expensive to shift its processing to adjust to drained weight, there is evidence that industry could comply quickly and without significant costs. For example, shippers of prepackaged poultry calculate different tares for batches of their products sent to different States. For those States that have had a drained weight regulation, such as Michigan, product has been sufficiently underlabeled to insure a high level of compliance. Some State inspectors even claim that shippers of prepackaged products calculate different tares on their products on a State-by-State and even a county-by-county basis. For example, Chicago has used a drained weight system, while the State of Illinois has followed a dry tare procedure.

Thus, manufactures could comply with drained weight regulations. However, moving to drained weight would probably increase costs to retailers due to additional reweighing and rewrapping of packages that routinely would have to be opened during inspection and due to more frequent monitoring of the meat counter by the retailer to find and rewrap packages with excessive drainage.

The additional costs to retailers nationally would be fairly small in view of the fact that a number of jurisdictions are already opening packages for at least some meat and poultry products to determine a wiped dry tare.[6]

(c) Concerns of State and Local Enforcement Agencies

The results of a survey by ESCS during its study indicate that State and local enforcement officials now vary in their preference for a definition of "tare" in a net weight regulation. Most non-Federal enforcement agencies opposed the 1973 proposal because it was believed that free liquid should not be included in net weight. Then in 1977, after the Supreme Court decision in *Jones* v. *Rath Packing Company,* the State of California petitioned FSQS to change its regulations to adopt a more enforceable standard at the State and local level. Officials from 47 other States, Washington, D.C., and American Somoa cosigned the petition. In December 1977, the Department proposed what was in essence a drained weight based standard.

The ESCS survey found that many States oppose adoption of the drained weight system because of the time it takes to complete the inspection. For example, in one test, the drained weight inspection of 10 packages of whole and cut-up chicken required over 2 hours. In contrast, the dry tare inspection of 10 similar packages would probably take only 10 to 20 minutes. This is a significant problem considering size of the staffs and budgets of such agencies.

The number of inspectors in most States is fairly low. Twenty-two States and four local jurisdictions reported to ESCS that they had 14 or fewer inspectors; 11 States had between 15 and 20 inspectors; and eight States reported more than 50. Budgets for State weights and measures inspection are also modest: 20 States estimated that less than $100,000 was spent on the activity; 14 States budgeted between $100,000 and $999,999; and only one State reported more than $1 million. These figures may be under-stated since many local government inspectors and budgets were not included.

The Department also takes special cognizance that most State and local agencies responding to the ESCS survey did not believe their budgets would be increased if drained weight regulations were adopted. Of the 45 agencies responding, 31 reported their State would not appropriate more money for net weight inspection, while only five felt their budgets would be increased, and nine gave no opinion or were unsure. Thus, the Department concluded that adoption of a drained weight system would be likely to result in decreased inspection capabilities at the State and local levels.

An additional cost to State and local weights and measures agencies would be the cost of sieves and receiving pans in order to carry out drained weighed procedures. Each inspector would need a 12" diameter and a 8" diameter #8 stainless steel sieve and two receiving pans. The total cost per inspector would be about $263. Assuming the number of State and local inspectors to be about 1,600, the total cost to the various State programs would be about $420,800.

Under the proposed regulations, these utensils would still be required to test products packed in non-usable media. The Department recognizes this cost, but it appears that a drained weight system is appropriate for such products. The total cost is expected to be somewhat less, as some State agencies already use sieves and pans. Additionally, not every inspector would need a set, as only a very small percentage of meat and poultry food products are packed in non-usable media.

(d) Concerns of the Department

A major USDA concern in considering the drained weight approach is centered around the economic effect of the regulation. As was discussed earlier, a general drained weight system would cause the cost per pound of all meat and poultry food items to increase a few cents. Even though there may be no increase in the real price per drained weight pound, any increase in the

labeled price per pound would be picked up and incorporated in the Consumer Price Index (CPI) (for those meat and poultry items that are priced). Moreover, a general drained weight system might increase the real cost slightly because of increased retailer repackaging.

The Department sees no justification in now proposing to approve a general drained weight regulation which would lessen the number of weight inspections by State and Federal inspection personnel and cause an increase in the Consumer Price Index.

(e) Whether or Not to Include Absorbed Liquid as Part of the Tare Weight

Having decided to propose to include free liquid as part of net weight for products packaged in usable liquid, the Department has considered whether the liquid absorbed by the packaging material should be included as part of the tare weight or as part of the net weight. In deciding to make alternative proposals on this question, the Department observes that either option is considered relatively easy to enforce at retail, and State officials and industry have had experience in operating under both systems.

By excluding liquid absorbed by the packaging materials from net weight, the Department believes there would be less chance of consumer deception, as well as incentive to industry to reduce added liquids during processing. In addition, the consumer cannot judge how much liquid is absorbed into the packaging, while the amount of free liquid is readily apparent. By including the liquid absorbed by the packaging material as part of the net weight, the use of absorbent packaging materials by producers would be encouraged. This appears to be desired by some consumers because it reduces the amount of liquid that may be free in the package. In view of these conflicting consumer interests, public comment is especially welcomed to assist in determining which of these two options should be adopted in a final regulation.

3. *Moisture Loss.* Present regulations allow for "reasonable variations" caused by loss or gain of moisture during good distribution practices or by unavoidable deviations in good manufacturing practices. Like the 1977 proposal, this proposal would eliminate any allowance for moisture loss, but allow specified numerical variations which are based upon unavoidable deviations during manufacture.[7] The lack of specificity of the term "reasonable variations" has hampered some States' net weight enforcement efforts. The ESCS study observed that for most meat and poultry products there is far more moisture loss due to seepage into the package, than due to evaporation. This is attributable to strong industry compliance with good distribution practices.

Industry comments on the ESCS study vary on this issue. Most agree with the study. However, they indicate a problem does exist with some nonhermetically sealed consumer packaged meat and poultry products and with bulk shipments of meat and poultry products where moisture loss can range from 1.6 percent to 3.6 percent.

USDA agrees that some products may exhibit particular problems with moisture loss due to evaporation. However, no allowance is specifically being made for such products in this proposal. The Department will consider proposing, however, at a later date, a weight allowance for a moisture loss for a particular product class upon a sufficient showing of the need for such an allowance. The Department, therefore, requests data on affected products to determine if regulations providing for a moisture loss allowance for a particular product class should be proposed.

Other industry representatives argued in comments following the ESCS study that the Agency is required by the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide in its regulations allowances for reasonable variations caused by the loss or gain of moisture (21 U.S.C. 453(h)(5) and 21 U.S.C. 601(n)(5)). The Department has determined that these provisions are permissive and neither require the allowance of any variations, nor specify the basis for any reasonable variations the Department determines to prescribe. The Department also reiterates that the reasonable variations that are being proposed are based on the variations in processing, and that reasonable variations for moisture loss may be proposed to be allowed for specific product classes dependent upon submissions following this proposal. The proposed allowable variations range from about 1 percent for larger containers to about 11 percent for smaller containers.

4. *Quality Control.* Unlike the 1977 proposal, the current proposal does not impose any specific quality control requirements to assure compliance with the net weight regulations. The Department has addressed the issue of quality control on a more general basis through its voluntary quality control regulations, which were proposed on September 13, 1979 (44 FR 53526–34).

5. *Sampling Procedures.* This proposal would provide sampling procedures for enforcement purposes which are not included in the Department's current regulations, and which differ from those proposed in 1977. The sampling plan reflects FSQS' consultation with the National Bureau of Standards concerning the development of appropriate statistically sound sampling procedures. The current proposal would determine sample sizes to be examined based on lot size, generally proposing sample sizes of 10 containers for a lot size of 250 containers or less, 30 containers for a lot size of 251 through 150,000 containers, and 50 containers for a lot size of more than 150,000 containers. A lot is defined as one type and style of product produced by one official establishment and bearing identical labeling (including the same net weight statement) and available for inspection at one place at one time, except that random weight packages may have differing statements of net weight. The size of the lot may be determined by the official establishment for product on the premises, but shall not exceed the production of one shift. For the lot to be in compliance, the weight of all of the samples must equal or exceed the declared net weight. In addition, each of the individual sample packages must be within the appropriate allowable variation, with one exception. For lots where 50 samples are required, one of the individual sample packages may be outside of the appropriate allowable variation.

It is the policy of the Department and FDA to adopt uniform net weight proposals where possible. In the instance of lot sampling, the proposals differ. FDA is also proposing sample sizes of 10, 30, and 50 depending on the number of packages in the lot, but is proposing a sample size of 30 containers for a lot of 251 to 3,200 containers, and a sample size of 50 containers when lot sizes exceed 3,200 units.

While these sample sizes differ in terms of the lot sizes, the statistical reliability of the two procedures is similar. This difference is due to the differing types of inspection performed by the two agencies. The Department, using a continuous inspection procedure, has ready access to meat and poultry food products during processing and packaging and to related records in order to assure correct labeling. FDA inspectors, on the other hand, do not

[7] The 1977 proposal contained variations providing for larger deviations for heterogenously manufactured product than for homogeneous product. This policy is not continued in the present proposal. The Department has determined that the system created unnecessary enforcement problems.

have such access to product or records and generally must draw samples from a lot or lots stored in warehouses.

6. *Bulk Packages.* As in the 1977 proposal, this proposal would continue to require net weight labels on immediate containers of bulk shipments at the producing establishment and after the product is shipped from that establishment. However, allowable variations for bulk packages are provided in the current proposal. This provision is in response to the comments received on the 1977 proposal which did not provide for such variations.

7. *Out of Compliance Product.* The proposed departmental regulations contain provisions for relabeling or reprocessing lots that fail to meet the net weight labeling requirements.

8. *Other Considerations.* The proposed regulation would eliminate the existing exemptions for placement and declaration of the net weight statement on shingle-packed bacon. The elimination of these exemptions was also proposed in 1977. As we stated in that proposal, the reason for such exemptions is that bacon has historically been labeled in such a manner. However, it appears that the consumers' interest in meaningful labeling would be served better if such packages were to conform to the net weight labeling requirements applicable to the vast majority of meat food products. Therefore, it is proposed that these exemptions be terminated.

Under the proposal, small packages (less than ½ ounce net weight) would be exempt from bearing statements of net weight or measure, provided that their shipping containers bore net weight statements that were in accord with the regulations. Such exemption is permitted under the Acts and is currently in the meat inspection regulations. However, changes have been made in the proposed regulations to clarify this exemption. For consistency, this exemption has also been extended to poultry products. Additionally, it is proposed that if an establishment wishes to place a net weight statement on a small package, such statement would be exempt from the normal type size, dual declaration, and placement requirements. This exemption is based upon the lack of labeling space inherent on such small packages.

The definitions for "random weight packages" and for "standard weight packages" would be clarified. Under the proposal, a "random weight package" would be defined as one of a lot, shipment or delivery which contains varying net weights and no fixed weight pattern. A "standard weight package" would be defined as one of a lot, shipment or delivery which contains a fixed weight pattern or the same preprinted weight statement on the labeling.

An optional provision to allow the tare weight to be printed on the labeling is being proposed for products packaged totally with impervious packaging materials and not packed with a non-usable medium.

Consultations

For several years, the Department and FDA have been attempting to develop jointly regulations on a net weight standard to assure uniformity in enforcement at the Federal, State and local levels. Joint discussions with the National Bureau of Standards were held, both in 1978, and prior to the development of this proposal. There has been a concerted effort to develop consistent regulations to the fullest extent possible within the authorities and enforcement capacity of the two agencies.

Also, in the development of this proposal, the Department has consulted with the Meat and Poultry Inspection Advisory Committee. During those consultations, the Committee recommended that the Department offer the alternative of a drained weight tare in the proposal. While a specific alternative has not been cited, the Department will carefully consider any comments which are received on this matter in determining a final rule. While the Committee's views have been taken into consideration during the development of this proposal, it has been agreed that this proposal will be presented to them for fuller comment.

Options Considered

In the development of this proposal, the Department has considered a number of alternative approaches, each of which is discussed more fully in the Draft Impact Analysis published as an appendix at the end of this proposal. These include, in addition to the current proposal, (1) a continuation of the present system, (2) the 1973 proposal, (3) the 1977 proposal, (4) the Grocery Manufacturers proposal, (5) a proposal currently being drafted by a committee of the Codex Alimentarius, and (6) the "Swedish" method for declaring "Net Weight at Time of Pack." The decision to publish the current proposal was based upon the Department's overall assessment of the compliance, enforcement, and economic factors previously discussed.

In the text of the proposal below, italics have been used to indicate those portions which relate to the alternatives for the inclusion or exclusion of liquid absorbed by the packaging materials as part of the net weight.

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

Accordingly, Part 317 of the Federal meat inspection regulations (9 CFR Part 317) would be amended as set forth below:

1. Section 317.2(h) (9 CFR 317.2(h)) would be amended by revising subparagraphs (1) and (2), adding a new sentence to the end of subparagraph (5), revising subparagraph (9)(ii), deleting subparagraph (9)(iv), and revising subparagraphs (11) and (13) to read as follows:

§ 317.2 Labels: definition; required features.

* * * * *

(h) (1) The statement of net quantity of contents shall appear, except as otherwise permitted under this paragraph (h), on the principal display panel of all containers to be sold at retail intact, in conspicuous and easily legible boldface print or type in distinct contrast to other matter on the container, and shall be declared in accordance with the provisions of this paragraph (h). A tare weight, as defined in § 317.20(g), may be printed adjacent to the statement of net quantity of contents when the product is packaged totally with impervious packaging material and is not packed with a non-usable medium.

(2) The statement as it is shown on a label shall not be false or misleading and shall express an accurate statement of the quantity of contents of the containers, exclusive of tare weight as defined in § 317.20(g); and variations from the net weight stated on the label, as described in § 317.19, are found to be reasonable and are allowable.

* * * * *

(5) * * * Subparagraph (9) of this paragraph (h) permits certain exceptions from the provisions of this subparagraph for margarine packages, and subparagraph (12) of this paragraph (h) permits certain exceptions from the provision of this subparagraph for multi-unit packages.

* * * * *

(9) * * *

(ii) Labels for small packages exempt from the requirements for a net weight statement under subparagraph (9)(i) of this paragraph (h) shall also be exempt from any type size, dual declaration, and placement requirements of this paragraph (h).

* * * * *

(iv) [Deleted]

* * * * *

(11) For the purpose of this section, a "random weight package" is a package which is one of a lot, shipment, or delivery of packages of the same product with varying net weights and with no fixed weight pattern.

* * * * *

(13) Shingle-packed sliced bacon cartons containing product weighing other than 8 ounces, 1 pound, or 2 pounds shall have the statement of the net weight shown with the same prominence as the most conspicuous feature.

* * * * *

2. Section 317.19 (9 CFR 317.19) would be redesignated as § 317.23 (9 CFR 317.23).

3. New §§ 317.18–317.22 (9 CFR 317.18–317.22) would be added to Part 317, and the Table of Contents would be amended accordingy, to read as follows:

Sec.
317.18 Quantity of contents labeling.
317.19 Reasonableness of net weight variations.
317.20 Definitions.
317.21 Procedure for determining net weight compliance.
317.22 Handling of failed product.

§ 317.18 Quantity of contents labeling.

Sections 317.18 through 317.22 of this Part prescribe the procedures to be followed for determining net weight compliance and prescribe the allowable variations from the declared net weight on the labels of immediate containers of products in accordance with § 317.2(h) of this Part.

§ 317.19 Reasonableness of net weight variations.

The net weight variations from the net weight stated on the label, which are set forth in Table 3 of § 317.21 of this Part, are found to be reasonable when determined in accord with the definitions and procedures prescribed in § 317.20 and 317.21 of this Part for products located in the producing establishment or anywhere else in the course of distribution.

§ 317.20 Definitions.

For the purpose of §§ 317.18 through 317.22 of this Part, the following terms and definitions shall apply:

(a) "Sample." A set of randomly selected packages, packaging material or containers, from a lot of product.

(b) "Lot." One type and style of product produced by one official establishment and bearing identical labeling (including the same net weight statement) and available for inspection at one place at one time; except that random weight packages may have differing statements of net weight. The size of the lot may be determined by the official establishment for product on the premise, but shall not exceed the production of one shift.

(c) "Packaging material and container." The immediate container and any other inedible material used to close, enclose, label, or mark the product. Impervious packaging material is material which does not absorb liquids such as water and oil; otherwise, it is pervious.

(d) "Usable medium." Any packing substance added to the package, including but not limited to broth, stock, agar, and gelatin, that is commonly used in preparing the product for consumption or that is an integral part of the finished product.

(e) "Non-usable medium." Any liquid packing substance added to the package, including but not limited to water, curing solutions, brine and vinegar, commonly discarded before consumer preparation and/or serving.

(f) "Gross weight." The total weight of the unopened package, that is, the container and all its contents.

(g) "Tare weight." The weight of the packaging materials and container, *and any liquids absorbed by the packaging material,* and any non-usable media that was added at the time of packaging.

(h) "Net weight." The gross weight minus the tare weight.

(i) "Standard weight package." A package which is one of a lot, shipment, or delivery of package of the same product with a fixed weight pattern or the same preprinted net weight statement on the labeling of each package.

(j) "Random weight package." A package which is one of a lot, shipment, or delivery of packages of the same product with varying net weights and with no fixed weight pattern.

§ 317.21 Procedure for determining net weight compliance.

The following procedure is for determining net weight compliance:

(a) Select the proper size sample for determining the net weight as follows:

(1) Randomly select 10 packages as a sample from:

(i) Any lot of product containing 250 packages or less for sale at retail, or

(ii) Any lot of product containing 250 packages or less not for sale at retail and each package weighing 30 pounds or less, or

(iii) Any size lot of product in packages not for sale at retail and each package weighing more than 30 pounds.

(2) Randomly select 30 packages as a sample from:

(i) Any lot of product containing more than 250 packages but not more than 150,000 packages for sale at retail, or

(ii) Any lot of product containing more than 250 packages not for sale at retail and each package weighing 30 pounds or less.

(3) Ramdomly select 50 packages as a sample from any lot containing more than 150,000 packages of product for sale at retail.

(b) Determine the gross weight as follows:

Weight each package in the net weight sample while filled and unopened to determine its gross weight.

(c) Determine the tare weight as follows:

(1) For standard weight packages of products, packaged totally with impervious packaging material and packed with usable media, or no packing medium except products packaged in glass containers.

(i) Outside the official establishment: Tare weight printed on the labeling may be used at the option of the compliance personnel. Otherwise, the tare weight shall be the average weight of the packaging material and containers in the tare weight sample, with the total number of packages in the tare weight sample determined by randomly selecting three packages from the net weight sample and then using Table 1 below. The tare weight of each package in the tare weight sample is calculated by emptying the contents of the filled container, rinsing and wiping the packaging material and container clean and dry, and weighing the empty container and packaging material.

(ii) In the official establishment: The tare weight shall be the average weight of the packaging material and container in the tare weight sample, with the total number of containers and packaging materials in the tare weight sample determined by randomly selecting three containers and packaging materials and then using Table 1 below. The tare weight may be determined by weighing unfilled containers and packaging material. Otherwise, the tare weight shall be determined by emptying the contents of filled containers, rinsing and wiping the packaging material and container clean and dry, and weighing the empty packaging material and container. For packages bearing a preprinted tare weight statement, the tare weight shall be determined upon receipt of labeling into the official establishment by weighing a randomly selected sample of 30 unfilled packaging materials and containers. The average weight of the sample packaging materials and containers shall be the tare weight.

(2) For standard weight packages of products, packaged totally or partially with pervious packaging material, or totally with impervious packaging material and packed with any non-usable medium, except products packaged in glass containers: The tare weight shall be the average weight of the packaging material and container *and any absorbed liquids,* and the weight of non-usable media in the tare weight sample, with the total number of packages in the tare weight sample determined by randomly selecting three packages and then using Table 1 below. The weight of non-usable media is determined as follows: Place the product on a U.S. Standard Number 8 mesh screen, 8 inches in diameter for product less than 3 pounds, and 12 inches in diameter for product 3 pounds and over, and allow it to drain 2 minutes. Then remove the solid portion of the product from the screen, weigh the screen and the drained liquid, and subtract the weight of the dry screen.

Table 1.—*Tare Weight—Standard Weight Packages*

If the difference in the weight of the container and packaging material between the heaviest and lighest of the initial 3 packages is—	Then the total number of containers and packaging materials to be in the sample for each lot is—
0 to 1/8 oz. (0 to 3.54 gms)	3
3/16 oz (5.32 gms)	6
1/4 oz. (7.09 gms)	9
5/16 oz. (8.86 gms)	[1]12
5/8 oz. or more (10.63 gms) or more	[1]15

[1]Only 10 packages are needed if a sample of 10 packages is required for net weight purposes under § 317.21(a)(1).

(3) For random weight packages of products packaged totally with impervious packaging material and packed with usable media or no packing medium, except products packaged in glass containers:

(i) Outside the official establishment: A tare weight printed on the labeling may be used at the option of the compliance personnel. Otherwise, the tare weight for each package in the net weight sample shall be the weight of the packaging material and container of that individual package. The tare weight of each package is calculated by emptying the contents of the filled container, rinsing and wiping the packaging material and container clean and dry, and weighing the empty container and packaging material.

(ii) In the official establishment: In circumstances where identical containers and packaging material is to be used for the entire lot, the tare weight may be the average weight of a number of the unfilled packaging materials and containers equal to the number of packages in the net weight sample. Otherwise, the tare weight for each package in the net weight sample shall be the weight of the packaging material and container of that individual package. The tare weight of each package is calculated by emptying the contents of filled container, rinsing and wiping the packaging material and container clean and dry, and weighing the empty packaging material and container. For packages bearing a pre-printed tare weight statement, the tare weight shall be verified upon receipt of labeling into the official establishment by weighing a randomly selected sample of 30 unfilled packaging materials and containers. The average weight of the sample packaging materials and containers shall be the tare weight.

(4) For random weight packages of products, packaged totally or partially with pervious packaging material, or totally with impervious packaging material and packed with an non-usable medium, except products in glass containers: The tare weight of each package in the net weight sample shall be the weight of the packaging material and container *and any absorbed liquids,* and the weight of non-usable media of that individual package. The weight of non-usable liquid media is determined as follows: place the product on a U.S. Standard Number 8 mesh screen, 8 inches in diameter for product less than 3 pounds, and 12 inches in diameter for product 3 pounds and over, and allow it to drain 2 minutes. Then remove the solid portion of the product from the screen, weigh the screen and drained liquid, and subtract the weigh of the dry screen.

(5) For glass containers packed with usable media or no packing medium:

(i) Outside the official establishment: The tare weight shall be the average weight of the containers in the tare weight sample. The total number of containers in the tare weight sample is initially determined by selecting six containers from a lot whose net weight sample size is 10 containers; selecting 12 containers from a lot whose net weight sample size is 30 containers; and selecting 18 containers from a lot whose net weight sample size is 50 containers. The tare weight of each initial sample container is calculated by emptying the contents of the filled container, rinsing and wiping the container clean and dry, and weighing the empty container. Then the io of the range between the lowest and highest gross weights of the filled initial samples (RG) and the range between the lowest and highest tare weights of the initial sample (RT) is calculated. Based on the RG/RT io, the total number of containers in the tare weight sample shall be in accordance with Table 2 below. The tare weights of the additional sample containers, if any, are then calculated in the same manner used for the initial sample containers.

(ii) In the official establishment: The tare weight shall be the average weight of the containers in the tare weight sample. The total number of containers in the tare weight sample is determined by the procedure detailed in paragraph (c)(5)(i) of this section, except that, in calculating tare weight, identical as-yet unfilled containers from the same lot may be used in lieu of emptying filled sample containers.

(6) For glass containers packed with non-usable media: The tare weight shall be the average weight of the containers and the weight of non-usable media in the tare weight sample. The total number of containers in the tare weight sample is determined by the procedure detailed in paragraph (c)(5)(i) of this section. The weight of non-usable media is determined as follows: Place the product on a U.S. Standard Number 8 mesh screen, 8 inches in diameter for product less than 3 pounds, and 12 inches in diameter for product 3 pounds and over, and allow it to drain 2 minutes. Then remove the solid portion of the product from the screen, weigh the screen and the drained liquid, and subtract the weight of the dry screen.

Table 2.—*Tare Weight—Glass Containers*

If the RG/RT io is—	And the Net Weight Sample Size is—		
	10	30	50
	then, the total number of containers to be in the tare weight sample for each lot is—		
0.2 or less	10	30	50
0.21 to 0.40	10	29	49
0.41 to 0.60	10	[illegible]	[illegible]
0.61 to 0.80	[illegible]	26	[illegible]
0.81 to 1.00	8	24	40
1.01 to 1.20	[illegible]	23	37
1.21 to 1.40	[illegible]	21	34
1.41 to 1.60	7	19	31
1.61 to 1.80	6	17	28
1.81 to 2.00	6	15	25
2.01 to 2.20	[illegible]	14	23
2.21 to 2.40	[illegible]	13	21
2.41 to 2.60	6	12	19
2.61 or more	6	12	18

(d) Determine the net weight. Subtract the tare weight determined in paragraph (c) from the gross weight of each package in the net weight sample as determined in paragraph (b). The result

is the net weight of each package in the net weight samples.

(e) Determine compliance.

(1) For standard weight packages, average the net weight of all of the packages in the net weight sample. If the average net weight of a sample consisting of:

(i) 10, 30, or 50 packages is less than the labeled weight, the lot fails.

(ii) 10 or 30 packages is at least the labeled net weight, determine the package which has the lowest net weight and calculate the amount by which that package varies from the labeled net weight. Compare that variation with the allowed variation defined for the applicable weight group in Table 3 of this paragraph. If the variation is equal to or less than that in Table 3, the lot passes; if the variation is greater than that in Table 3, the lot fails.

(iii) 50 packages is at least the labeled net weight, determine the two packages which have the lowest net weights, and calculate the amounts by which those packages vary from the labeled net weight. Compare those variations with the allowed variation defined for the applicable weight group in Table 3 of this paragraph. If the variations of both packages are greater than that in Table 3, the lot fails.

(2) For all random weight packages, determine the difference between the total actual net weight of all of the packages in the net weight sample and the total labeled net weight of all of the packages in the net weight sample. For a net weight sample consisting of:

(i) 10, 30, or 50 packages, if the total actual weight is less than the total declared weight, the lot fails.

(ii) 10 or 30 packages, if the total actual weight equals or exceeds the total labeled net weight, determine the package which has the greatest variation below its labeled net weight. Compare that variation with the allowed variation defined in Table 3 of this paragraph for the lowest weight group represented in the sample. If the variation is equal to or less than that in Table 3, the lot passes; if the variation is greater than that in Table 3, the lot fails.

(iii) 50 packages, if the total actual weight equals or exceeds the total labeled net weight, determine the two packages which have the greatest variations below their labeled net weight. Compare those variations with the allowed variation defined in Table 3 of this paragraph for the lowest weight group represented in the sample. If the variations of both packages are greater than that in Table 3, the lot fails.

(3) In the official establishment, for packages bearing a pre-printed tare weight statement, if the average weight of the sample packaging materials and containers is equal to or less than the printed tare weight statement, the lot passes. If the average weight of the sample packaging materials and containers is greater than the printed tare weight, the lot fails.

Table 3.—*Allowable Variations for Immediate Containers*

Avoirdupois units			Metric units	
Labeled weight	Allowed variation		Labeled weight	Allowed variation
Pounds or ounces	Decimal pounds	Fractional ounces	Grams	Grams
0 to [1] 0.026 lb	0.001		0 to 11.6	0.5
0 to 0.41 oz				
0.026[2]+ to 0.04 lb	0.002	1/32	11.6+ to 18	1
0.041+ to 0.64 oz				
0.04+ to 0.08 lb	0.004	1/16	18+ to 36	2
0.64+ to 1.28 oz				
0.08+ to 0.12 lb	0.008	1/8	36+ to 54	4
1.28+ to 1.92 oz				
0.12+ to 0.18 lb	0.012	5/16	54+ to 82	5
1.92+ to 2.88 oz				
0.18+ to 0.26 lb	0.016	1/4	82+ to 118	7
2.88+ to 4.16 oz				
0.26+ to 0.34 lb	0.020	5/16	118+ to 154	9
4.16+ to 5.44 oz				
0.34+ to 0.46 lb	0.024	3/8	154+ to 209	11
5.44+ to 7.36 oz				
0.46+ to 0.58 lb	0.028	7/16	209+ to 263	13
7.36+ to 9.28 oz				
0.58+ to 0.70 lb	0.032	1/2	263+ to 318	15
9.28+ to 11.20 oz				
0.70+ to 0.84 lb	0.036	9/16	318+ to 381	16
11.20+ to 13.44 oz				
0.84+ to 0.94 lb	0.040	5/8	381+ to 426	18
13.44+ to 15.04 oz				
0.94+ to 1.08 lb	0.044	11/16	426+ to 490	20
15.04+ to 17.28 oz				
1.08+ to 1.26 lb	0.048	3/4	490+ to 572	22
1.26+ to 1.40 lb	0.052	13/16	572+ to 635	24
1.40+ to 1.54 lb	0.056	7/8	635+ to 698	25
1.54+ to 1.70 lb	0.060	15/16	698+ to 771	27
1.70+ to 1.88	0.064	1	771+ to 852	29
1.88+ to 2.14	0.070	1 1/8	852+ to 971	32
2.14+ to 2.48	0.078	1 1/4	971+ to 1.125	35
2.48+ to 2.76	0.086	1 3/8	1.125+ to 1.350	40
2.76+ to 3.20	0.094	1 1/2	1.350+ to 1.600	45
3.20+ to 3.90	0.11	1 3/4	1.600+ to 1.800	50
3.90+ to 4.70	0.12	2	1.800+ to 2.100	55
4.70+ to 5.80	0.14	2 1/4	2.100+ to 2.640	65
5.80+ to 6.80	0.15	2 1/2	2.640+ to 3.080	70
6.80+ to 7.90	0.17	2 3/4	3.080+ to 3.800	80
7.90+ to 9.40	0.19	3	3.800+ to 4.400	85
9.40+ to 11.70	0.22	3 1/2	4.400+ to 5.200	100
11.70+ to 14.30	0.25	4	5.200+ to 6.800	115
14.30+ to 17.70	0.28	4 1/2	6.800+ to 8.20	130
17.70+ to 23.20	0.31	5	8.20+ to 10.60	145
23.20+ to 31.60	0.37	6	10.60+ to 14.30	170
31.60+ to 42.40	0.44	7	14.30+ to 19.25	200
42.40+ to 54.40	0.50	8	19.25+ to 24.70	230
54.40+	1%		24.70+	1%

[1] "To" means "to and including."
[2] 0.026+ means "greater than 0.026."

§ 317.22 Handling of failed product.

Any lot of product which fails the requirements of § 317.21 shall be handled by one of the following:

(a) A lot located in an official establishment may be relabeled with a proper net weight statement and be reinspected, in accordance with the requirements of this Part.

(b) A lot located in an official establishment may be reprocessed provided such use does not cause the finished meat food product to be adulterated or misbranded.

(c) Product outside of an official establishment may be reweighed and remarked with proper net weight statement under the supervision of Federal, State or local inspection officials, provided that such reweighing and remarking shall not deface, cover,

or destroy any other marking or labeling requirements of this Subchapter.

§ [Redesignated from § 317.19]

(Secs. 1, 21, 34 Stat. 1260, as amended; 21 U.S.C. 601, 621, as amended; 42 FR 35625, 35626)

PART 381—POULTRY PRODUCTS INSPECTION REGULATION

Further, the poultry products inspection regulations (9 CFR Part 381) would be amended as set forth below.

1. Section 381.121 (9 CFR 381.121) would be amended by revising the first sentence of paragraph (a), deleting the first sentence of paragraph (b), adding a new sentence to the end of paragraph (c)(1), adding a new sentence to the end of paragraph (c)(5), revising paragraphs (c) (6) and (9), and adding a new paragraph (c)(10) to read as follows:

§ 381.121 Quantity of contents.

(a) The label shall bear a statement of the quantity of contents in terms of net weight or measure as provided in paragraph (c)(5) of this section. * * *

* * * * * *

(c)(1) * * * A tare weight, as defined in § 381.121c(g), may be printed adjacent to the statement of net quantity of contents when the product is packaged totally with impervious packaging material and is not packed with a non-usable medium.

* * * * * *

(5) * * * Subparagraph (8) of this paragraph (c) permits certain exceptions from the provisions of this subparagraph for multi-unit packages.

(6) The statement as it is shown on a label shall not be false or misleading and shall express an accurate statement of the quantity of contents of the container exclusive of tare weight as defined in § 381.121c; and variations from the net weight stated on the label, as defined in § 381.121b, are found to be reasonable and are allowable. The statement shall not include any term qualifying a unit of weight, measure, or count such as "jumbo quart," "full gallon," "giant quart," "when packed," "minimum" or words of similar import, except as provided in paragraph (b) of this section.

* * * * * *

(9) The following exemption from the requirements contained in this section is hereby established:

(i) Individually wrapped and labeled packages of less than ½ ounce net weight which are in a shipping container, need not hear a statement of net quantity of contents as specified in this section when the statement of net quantity of contents on the shipping container meets the requirements of this section.

(ii) Labels for small packages exempt from the requirements for a net weight statement under subparagraph (9)(i) of this paragraph (c) shall also be exempt from any type size, dual declaration, and placement requirements of this section.

(10) For the purpose of this section, a "Random weight package" is a package which is one of a lot, shipment, or delivery of packages of the same product with varying net weights and with no fixed weight pattern.

2. New §§ 381.121a–381.121e (9 CFR 381.121a–381.121e) would be added to Part 381, and the Table of Contents would be amended accordingly, to read as follows:

Sec.

381.121a Quantity of contents labeling.
381.121b Reasonableness of net weight variations.
381.121c Definitions.
381.121d Procedure for determining net weight compliance.
381.121e Handling of failed product.

§ 381.121a Quantity of contents labeling.

Sections 381.121a through 381.121e prescribe the procedures to be followed for determining net weight compliance and prescribe the allowable variations from the declared net weight on the labels of immediate containers of products in accordance with § 381.121 of this Subpart.

§ 381.121b Reasonableness of net weight variations.

The net weight variations from the net weight declared on the label statement, which are set forth in Table 3 of § 381.121d of this Subpart, are found to be reasonable when determined in accord with the definitions and procedures prescribed in §§ 381.121c and 381.121d of this Subpart for products located in the producing establishment or anywhere else in the course of distribution.

§ 381.121c Definitions.

For the purpose of sections 381.121a through 381.121e of this Subpart, the following terms and definitions shall apply:

(a) "Sample." A set of randomly selected packages, packaging material or containers, from a lot of product.

(b) "Lot." One type and style of product produced by one official establishment and bearing identical labeling (including the same net weight statement) and available for inspection at one place at one time; except that random weight packages may have differing statements of net weight. The size of the lot may be determined by the official establishment for product on the premises, but shall not exceed the production of one shift.

(c) "Packaging material and container." The immediate container and any other inedible material used to close, enclose, label, or mark the product. Impervious packaging material is material which does not absorb liquids such as water and oil, otherwise, it is pervious.

(d) "Usable medium." Any packing substance added to the package, including but not limited to broth, stock, agar, and gelatin, that is commonly used in preparing the product for consumption or that is an integral part of the finished product.

(e) "Non-usable medium." Any liquid packing substance added to the package, including but not limited to water, curing solutions, brine and vinegar, commonly discarded before consumer preparation and/or serving.

(f) "Gross weight." The total weight of the unopened package, that is, the container and all its contents.

(g) "Tare weight." The weight of the packaging materials and container, *and any liquids absorbed by the packaging material,* and any non-usable media that was added at the time of packaging.

(h) "Net weight." The gross weight minus the tare weight.

(i) "Standard weight package." A package which is one of a lot, shipment, or delivery of packages of the same product with a fixed weight pattern or the same preprinted net weight statement on the labeling of each package.

(j) "Random weight package." A package which is one of a lot, shipment, or delivery of packages of the same product with varying net weights and with no fixed weight pattern.

§ 381.121d Procedure for determining net weight compliance.

The following procedure is for determining net weight compliance:

(a) Select the proper size sample for determining the net weight as follows:

(1) Randomly select 10 packages as a sample from:

(i) Any lot of product containing 250 packages or less for sale at retail, or

(ii) Any lot of product containing 250 packages or less not for sale at retail and each package weighing 30 pounds or less, or

(iii) Any size lot of product in packages not for sale at retail and each package weighing more than 30 pounds.

(2) Randomly select 30 packages as a sample from:

(i) Any lot of product containing more than 250 packages but not more than 150,000 packages for sale at retail, or

(ii) Any lot of product containing more than 250 packages not for sale at retail and each package weighing 30 pounds of less.

(3) Randomly select 50 packages as a sample from any lot containing more than 150,000 packages of product for sale at retail.

(b) Determine the gross weight as follows:

Weigh each package in the net weight sample while filled and unopened to determine its gross weight.

(c) Determine the tare weight as follows:

(1) For standard weight packages of products, packaged totally with impervious packaging material and packed with usable media, or no packing medium except products packaged in glass containers.

(i) Outside the official establishment: Tare weight printed on the labeling may be used at the option of the compliance personnel. Otherwise, the tare weight shall be the average weight of the packaging material and containers in the tare weight sample, with the total number of packages in the tare weight sample determined by randomly selecting three packages from the new weight sample and then using Table 1 below. The tare weight of each package in the tare weight sample is calculated by emptying the contents of the filled container, rinsing and wiping the packaging material and container clean and dry, and weighing the empty container and packaging material.

(ii) In the official establishment: The tare weight shall be the average weight of the packaging material and container in the tare weight sample, with the total number of containers and packaging materials in the tare weight sample determined by randomly selecting three containers and packaging materials and then using Table 1 below. The tare weight may be determined by weighing unfilled containers and packaging material. Otherwise, the tare weight shall be determined by emptying the contents of filled containers, rinsing and wiping the packaging material and container clean and dry, and weighing the empty packaging material and container. For packages bearing a pre-printed tare weight statement, the tare weight shall be determined upon receipt of labeling into the official establishment by weighing a randomly selected sample of 30 unfilled packaging materials and containers. The average weight of the sample packaging materials and containers shall be selected sample of 30 unfilled packaging materials and containers. The average weight of the sample packaging materials and containers shall be the tare weight.

(2) For standard weight packages of products, packaged totally or partially with pervious packaging material, or totally with impervious packaging material and packed with any non-usable medium, except products packaged in glass containers: The tare weight shall be the average weight of the packaging material and container *and any absorbed liquids,* and the weight of non-usable media in the tare weight sample, with the total number of packages in the tare weight sample determined by randomly selecting three packages and then using Table 1 below. The weight of non-usable media is determined as follows: Place the product on a U.S. Standard Number 8 mesh screen, 8 inches in diameter for product less than 3 pounds, and 12 inches in diameter for product 3 pounds and over, and allow it to drain 2 minutes. Then remove the solid portion of the product from the screen, weigh the screen and the drained liquid, and substract the weight of the dry screen.

Table 1.—*Tare Weight—Standard Weight Packages*

If the difference in the weight of the container and packaging material between the heaviest and lightest of the initial 3 packages is—	Then the total number of containers and packaging materials to be in the sample for each lot is—
0 to ⅛ oz. (0 to 3.54 gms)	3
3/16 oz. (5.32 gms)	6
¼ oz. (7.09 gms)	9
5/16 oz. (8.86 gms)	[1]12
⅜ oz. or more (10.63 gms) or more	[1]18

[1] Only 10 packages are needed if a sample of 10 packages is required for net weight purposes under § 381.121d(a)(1).

(3) For random weight packages of products packaged totally with impervious packaging material and packed with usable media or no packing medium, except products packaged in glass containers:

(i) Outside the official establishment: A tare weight printed on the labeling may be used at the option of the compliance personnel. Otherwise, the tare weight for each package in the net weight sample shall be the weight of the packaging material and container of that individual package. The tare weight of each package is calculated by emptying the contents of the filled container, rinsing and wiping the packaging material and container clean and dry, and weighing the empty container and packaging material.

(ii) In the official establishment: In circumstances where identical containers and packaging material is to be used for the entire lot, the tare weight may be the average weight of a number of the unfilled packaging materials and containers equal to the number of packages in the net weight sample. Otherwise, the tare weight for each package in the net weight sample shall be the weight of the packaging material and container of that individual package. The tare weight of each package is calculated by emptying the contents of filled container, rinsing and wiping the packaging material and container clean and dry, and weighing the empty packaging material and container. For packages bearing a pre-printed tare weight statement, the tare weight shall be verified upon receipt of labeling into the official establishment by weighing a radomly selected sample of 30 unfilled packaging materials and containers. The average weight of the sample packaging materials and containers shall be the tare weight.

(4) For random weight packages of products, packaged totally or partially with pervious packaging material, or totally with impervious packaging material and packed with any non-usable medium, except products in glass containers: The tare weight of each package in the net weight sample shall be the weight of the packaging material and container *and any absorbed liquids,* and the weight of non-usable media of that individual package. The weight of non-usable liquid media is determined as follows: Place the product on a U.S. Standard Number 8 mesh screen, 8 inches in diameter for product less than 3 pounds, and 12 inches in diameter for product 3 pounds and over, and allow it to drain 2 minutes. Then remove the solid portion of the product from the screen, weigh the screen and the drained liquid, and substract the weight of the dry screen.

(5) For glass containers packed with usable media or no packing medium:

(i) Outside the official establishment: The tare weight shall be the average weight of the containers in the tare weight sample. The total number of containers in the tare weight sample is initially determined by selecting six containers from a lot whose net weight sample size is 10 containers; selecting 12 containers from a lot whose net weight sample size is 30 containers; and selecting 18 containers from a lot whose

net weight sample size is 50 containers. The tare weight of each initial sample container is calculated by emptying the contents of the filled container, rinsing and wiping the container clean and dry, and weighing the empty container. Then the ratio of the range between the lowest and highest gross weights of the filled initial samples (RG) and the range between the lowest and highest tare weights of the initial sample (RT) is calculated. Based on the RG/RT ratio, the total number of containers in the tare weight sample shall be in accordance with Table 2 below. The tare weights of the additional sample containers, if any, are then calculated in the same manner used for the initial sample containers.

(ii) In the official establishment: The tare weight shall be the average weight of the containers in the tare weight sample. The total number of containers in the tare weight sample is determined by the procedure detailed in paragraph (c)(5)(i) of this section, except that, in calculating tare weight, identical as-yet unfilled containers from the same lot may be used in lieu of emptying filled sample containers.

(6) For glass containers packed with non-usable media: The tare weight shall be the average weight of the containers and the weight of non-usable media in the tare weight sample. The total number of containers in the tare weight sample is determined by the procedure detailed in paragraph (c)(5)(i) of this section. The weight of non-usable media is determined as follows: Place the product on a U.S. Standard Number 8 mesh screen, 8 inches in diameter for product less than 3 pounds, and 12 inches in diameter for product 3 pounds and over, and allow it to drain 2 minutes. Then remove the solid portion of the product from the screen, weigh the screen and the drained liquid, and subtract the weight of the dry screen.

Table 2.—*Tare Weight—Glass Containers*

If the RG/RT ratio is—	And the net weight sample size is—		
	10	30	50
	then the total number of containers to be in the tare weight sample for each lot is—		
0.2 or less	10	[illegible]	50
0.21 to 0.40	10	[illegible]	[illegible]
0.41 to 0.60	10	[illegible]	[illegible]
0.61 to 0.80	[illegible]	[illegible]	[illegible]
0.81 to 1.00	8	[illegible]	[illegible]
1.01 to 1.20	[illegible]	[illegible]	37
1.21 to 1.40	8	[illegible]	[illegible]
1.41 to 1.60	7	[illegible]	31
1.61 to 1.80	[illegible]	17	28
1.81 to 2.00	6	15	[illegible]
2.01 to 2.20	6	14	[illegible]
2.21 to 2.40	6	13	[illegible]
2.41 to 2.60	[illegible]	12	[illegible]
2.61 or more	6	12	[illegible]

(d) Determine the net weight. Subtract the tare weight determined in paragraph (c) from the gross weight of each package in the net weight sample as determined in paragraph (b). The result is the net weight of each package in the net weight samples.

(e) Determine compliance.

(1) For standard weight packages, average the net weight of all of the packages in the net weight sample. If the average net weight of a sample consisting of:

(i) 10, 30, or 50 packages is less than the labeled weight, the lot fails.

(ii) 10 or 30 packages is at least the labeled net weight, determine the package which has the lowest net weight and calculate the amount by which that package varies from the labeled net weight. Compare that variation with the allowed variation defined for the applicable weight group in Table 3 of this paragraph. If the variation is equal to or less than that in Table 3, the lot passes; if the variation is greater than that in Table 3, the lot fails.

(iii) 50 packages is at least the labeled net weight, determine the two packages which have the lowest net weights, and calculate the amounts by which those packages vary from the labeled net weight. Compare those variations with the allowed variation defined for the applicable weight group in Table 3 of this paragraph. If the variations of both packages are greater than that in Table 3, the lot fails.

(2) For all random weight packages, determine the difference between the total actual net weight of all of the packages in the net weight sample and the total labeled net weight of all of the packages in the net weight sample. For a net weight sample consisting of:

(i) 10, 30, or 50 packages, if the total actual weight is less than the total declared weight, the lot fails.

(ii) 10 or 30 packages, if the total actual weight equals or exceeds the total labeled net weight, determine the package which has the greatest variation below its labeled net weight. Compare that variation with the allowed variation defined in Table 3 of this paragraph for the lowest weight group represented in the sample. If the variation is equal to or less than that in Table 3, the lot passes; if the variation is greater than that in Table 3, the lot fails.

(iii) 50 packages, if the total actual weight equals or exceeds the total labeled net weight, determine the two packages which have the greatest variations below their labeled net weight. Compare those variations with the allowed variation defined in Table 3 of this paragraph for the lowest weight group represented in the sample. If the variations of both packages are greater than that in Table 3, the lot fails.

(3) In the official establishment, for packages bearing a preprinted tare weight statement, if the average weight of the sample packaging materials and containers is equal to or less than the printed tare weight statement, the lot passes. If the average weight of the sample packaging materials and containers is greater than the printed tare weight, the lot fails.

Table 3.—*Allowable Variations for Immediate Containers*

Avoirdupois units			Metric units	
Labeled weight	Allowed variation		Labeled weight	Allowed variation
Pounds or ounces	Decimal pounds	Fractional ounces	Grams	Grams
0 to[1] 0.026 lb	0.001		0 to 11.6	0.5
0 to 0.41 oz				
0.026+[2] to 0.04 lb	0.002	1/32	11.6+ to 18	1
0.41+ to 0.64 oz				
0.04+ to 0.08 lb	0.004	1/16	18+ to 36	2
0.64+ to 1.28 oz				
0.08+ to 0.12 lb	[illegible]	1/8	36+ to 54	4
1.28+ to 1.92 oz				
0.12+ to 0.18 lb	0.012	3/16	54+ to 82	5
1.92+ to 2.88 oz				
0.18+ to 0.26 lb	0.016	1/4	82+ to 118	7
2.88+ to 4.16 oz				
0.26+ to 0.34 lb	0.020	5/16	118+ to 154	9
4.16+ to 5.44 oz				
0.34+ to 0.46 lb	0.024	[illegible]	154+ to 209	11
5.44+ to 7.36 oz				
0.46+ to 0.58 lb	0.028	7/16	209+ to 263	13
7.36+ to 9.28 oz				
0.58+ to 0.70 lb	0.032	[illegible]	263+ to 318	15
9.28+ to 11.20 oz				
0.70+ to 0.84 lb	0.036	9/16	318+ to 381	16
11.20+ to 13.44 oz				
0.84+ to 0.94 lb	0.040	5/8	381+ to 426	18
13.44+ to 15.04 oz				
0.94+ to 1.08 lb	0.044	1 1/16	426 to 490	20
15.04+ to 17.28 oz				

Table 3.—*Allowable Variations for Immediate Containers*—Continued

Avoirdupois units			Metric units	
Labeled weight	Allowed variation		Labeled weight	Allowed variation
Pounds or ounces	Decimal pounds	Fractional ounces	Grams	Grams
1.08+ to 1.26 lb	0.048	3/4	490+ to 572	22
1.26+ to 1.40 lb	0.052	13/16	572+ to 635	24
1.40+ to 1.54 lb	0.056	7/8	635+ to 698	25
1.54+ to 1.70 lb	0.060	15/16	698+ to 771	27
1.70+ to 1.88	0.064	1	771+ to 852	29
1.88+ to 2.15	0.070	1 1/16	852+ to 971	32
2.14+ to 2.48	0.078	1 1/4	971+ to 1.125	35
2.48+ to 2.76	0.086	1 3/8	1.125+ to 1.350	40
2.76+ to 3.20	0.094	1 1/2	1.350+ to 1.600	45
3.20+ to 3.90	0.11	1 3/4	1.600+ to 1.800	50
3.90+ to 4.70	0.12	2	1.800+ to 2.100	55
4.70+ to 5.80	0.14	2 1/4	2.100+ to 2.640	65
5.80+ to 6.80	0.15	2 1/2	2.640+ to 3.080	70
6.80+ to 7.90	0.17	2 3/4	3.080+ to 3.800	80
7.90+ to 9.40	0.19	3	3.800+ to 4.400	85
9.40+ to 11.70	0.22	3 1/2	4.400+ to 5.200	100
11.70+ to 14.30	0.25	4	5.200+ to 6.800	115
14.30+ to 17.70	0.28	4 1/2	6.800+ to 8.20	130
17.70+ to 23.20	0.31	5	8.20+ to 10.60	145
23.20+ to 31.60	0.37	6	10.60+ to 14.30	170
31.60+ to 42.40	0.44	7	14.30+ to 19.25	200
42.40+ to 54.40	0.50	8	19.25+ to 24.70	230
54.40+	1%		24.70+	1%

[1] "To" means "to and including."
[2] 0.026+ means "greater than 0.026."

§ 381.121e Handling of failed product.

Any lot of product which fails the requirements of § 381.121d shall be handled by one of the following:

(a) A lot located in an official establishment may be relabeled with a proper net weight statement and be reinspected, in accordance with the requirements of this Subpart.

(b) A lot located in an official establishment may be reprocessed provided such use does not cause the finished poultry product to be adulterated or misbranded.

(c) Product outside of an official establishment may be reweighed and remarked with a proper net weight statement under the supervision of Federal, State, or local inspection officials, provided that such reweighing and remarking shall not deface, cover, or destroy any other marking or labeling requirements of this Subchapter.

(Secs. 4 and 14, 71 Stat. 441, as amended; 21 U.S.C. 453 and 463; 42 FR 35625, 35626)

Done at Washington, D.C., on: August 1, 1980.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Services.

Appendix—Draft Impact Analysis

Date: July 15, 1980
Agency: USDA–FSQS
Contact: John McCutcheon
Phone: 202–447–6525
Decision Calendar: FSQS #10845

1. *Title:* Net Weight Labeling.

2. *Nature of Proposed Action:* The Food Safety and Quality Service (FSQS) proposes to amend the net weight labeling regulations for meat and poultry products (9 CFR 317.2(h) and 381.121). The current regulations require that:

The statement as it is shown on a label shall not be false or misleading and shall express an accurate statement of the quantity of contents of the container exclusive of the wrapper and packing substances. Reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity or contents shall not be unreasonably large.

The proposed regulation addresses the following specific issues:

(1) Free liquid (liquid which has separated itself from the product but which has not been absorbed by the packing material) would be included in a determination of the net weight of product except for those few products which are packed in substances which are normally discarded before consumer preparation and/or serving. With regard to including the liquid absorbed by the packaging material in the net weight, the proposal offers two alternatives. One alternative would exclude the weight of both packaging materials and liquid absorbed by packaging materials from the product's net weight. The other would exclude only the weight of packaging materials. FSQS is unable to choose between these two alternatives on the basis of the analysis presented in this impact statement. The agency will base its decision on information garnered from public comments on the proposal.

(2) Numerical allowable variations will replace the undefined "reasonable variations" allowed under current regulations for checking declared net weight accuracy. Adoption of numerical allowable variations would enable more effective enforcement of net weight regulations by State and local agencies.

(3) The proposed net weight rules and regulations for meat and poultry products set forth specific procedures for enforcement. Federally inspected plants would continue to have the option of using voluntary quality control programs to supplement inspection by Federal inspectors.

(4) Current exemptions for placement and declaration of the declared net weight on shingle packed bacon packages would be eliminated.

3. *Purpose and Need for Action:* This action will seve several purposes. First, by providing numerical allowable variations, it will insure that the net weight statement is as accurate as can be reasonably expected at the time meat and poultry products are purchased by consumers. Second, it will provide a standard procedure for State and local regulatory agencies to enforce strict net weight standards. Last, it will minimize substantive differences in net weight compliance procedures between the Food and Drug Administration and the Meat and Poultry Inspection Program of the Food Safety and Quality Service.

The need for this proposal is based on three developments, the first of which occurred in 1972 (Table 1). In the course of developing weights and measures regulations over the years, some state and local governments did not provide for any reasonable variation in net weight caused by moisture loss or gain during the course of good distribution practices, as is provided under Federal law. This difference did not become an issue until 1972 when local officials in California ordered "off sale" a federally inspected meat product with a net weight, as determined by the State procedure, below the declared net weight.

The food manufacturer of that product filed suit in the U.S. District Court for the Central District of California. A central issue was a State's authority over a product that met Federal requirements. In that case, *Rath Packing Company* v. *M. H. Becker,* 357 F. Supp. 529 (C. D. Cal. 1973), the District Court, in 1973, held that the Federal Meat Inspection Act preempts California and its political subdivisions from imposing net weight labeling requirements on federally inspected meat products that are in addition to or different from the Federal rules. Furthermore, the misbranding and mislabeling provisions of the Act were held to apply not only at the official establishment packing the product, but at all levels in the distribution chain, including the retail level. But, it was also held that the Federal regulation allowing "reasonable variations" with respect to net weight (9 CFR 317.2(h)(2)) was void due to vagueness.

This decision was appealed to the Ninth Circuit Court of Appeals. In October 1975, this Court affirmed the decision on preemption, but reversed the decision that the "reasonable variations" provision (9 CFR 317.2(h)(2)) was void due to vagueness (530 F.2d 1295 (9th Cir. 1975)).

The preemption issue was appealed by the State of California to the U.S. Supreme Court, which affirmed the Court of Appeals in March, 1977 (*Jones* v. *Rath Packing Company,* 430 U.S. 519 (1977)).

Table 1.—*Sequence of Events in the Regulation of Net Weight*

Year	Month	Event
1972		U.S. District Court action initiated—*Rath v. Becker et. al.*
1973		U.S. District Court rules that the Federal Meat Inspection Act preempts California from imposing net weight labeling requirements different from the Federal requirements and the "reasonable variations" regulation is void due to vagueness.
1973	Decem-ber.	USDA publishes the first net weight regulation proposal in response to court decision.
1974		USDA participates in a series of public meetings on the proposal.
1974		USDA began official dialogue with FDA, FTC and NBS concerning net weight issues.
1975	October	U.S. Court of Appeals upholds the decision on preemption, but overturns the decision on vagueness of the "reasonable variations" regulation.
1977	March	U.S. Supreme Court supports the concept of "Concurrent Jurisdiction," but affirms the decision on the Federal authority to preempt in *Jones* v. *Rath Packing.*
1977		States petition for revised Federal regulations on net weight.
1977	Decem-ber.	Second net weight proposal is published.
1978	February	Public hearings are held on the proposal.
1978	June	Comment period on the proposal closes.
1978	October	Consumer Federation of America study on net weight is completed for FSQS.
1978	Decem-ber.	GAO Report on net weight is released.
1979	January	FSQS asks ESCS to analyze the 1977 proposal.
1979	August	ESCS report completed and released for comment.
1979	October	Comment period study closes.

The second development occurred in December 1973 when the Department published a proposed regulation in response to the District Court's decision on vagueness of the "reasonable variations" allowed for net weight labeling (38 FR 33308–33313). Procedures were proposed for determining allowable net weight variation at the producing plant and during distribution. With numerical net weight variations, packers would have needed to target the fill-weight above the stated net weight to assure compliance at the processing plant and at retail outlets. Recoverable liquids that drained from the product would have been considered as part of the net weight. For compliance purposes, each federally inspected establishment packing immediate containers bearing net weight statements would have had to implement an FSQS-approved mandatory quality control program in accordance with specific recommendations contained in the proposal. The compliance test required that the average weight of the samples of a lot equal or exceed the declared weight. Appropriate sample allowances would have been permitted for products stamped at retail. In addition, the proposal would have eliminated the net weight labeling provisions (9 CFR 317.2 (h)) that exempt shingle packed bacon from the requirement of placing the net quantity of contents statement in pounds and ounces within the lower 30 percent of the principal display panel. The labeling requirement for bulk shipments was revised by requiring, at a minimum, a quantity count of the container contents.

Public hearings held during 1974 to explain this proposal revealed widespread dissatisfaction on the part of consumers, industry representatives and State and local weights and measures officials. Over 1,600 written comments on the proposal—from 21 consumer groups, 69 industry groups, and over 1,300 individuals, among others—expressed essentially the same dissatisfaction. Consumers generally objected to paying for water, blood and packing media; they wanted labels to state net weight of product contents, excluding these substances. There was also some objection to Federal preemption of State and local rules. Industry expressed three major complaints. First, the controls should be directed only to marked consumer-size packages, not bulk shipments. Second, the allowable variation was too "tight," and third, elimination of allowances for moisture lost through evaporation would require a shift to vacuum packaging.

The third development occurred following the U.S. Supreme Court decision in *Jones* v. *Rath Packing* in 1977 which upheld Federal preemption. California and 47 other States and territories petitioned the Department for a more enforceable net weight regulation. The petition argued that State inspectors could not determine whether the difference between the weight of the net contents and declared label weight on the package is reasonable without a definition of reasonable variation.

In response to the petition, consumer complaints, and comments about the 1973 proposal, FSQS published a new proposed net weight label regulation in the Federal Register on December 2, 1977 (Vol. 342, 61279–61284). Under this proposal, the declared net weight would be euqal to or less than the actual weight of the *usable* meat and poultry contents of the package at the time of purchase. Also, new allowable variation standards that could be enforced by State and local agencies would be provided. This meant that the free liquid in a package and substances absorbed by packaging materials would no longer be considered as part of the net contents. The agency proposed a set of specific allowable weight variations in place of the "reasonable variations" rule. For compliance purposes, all federally inspected meat and poultry establishments packing immediate containers bearing net weight statements would have to adopt a mandatory net weight quality control program. The proposal would also eliminate the exemptions for net weight label declaration and placement on shingle packed bacon (9 CFR 317.2 (h)).

The proposal was controversial for several reasons. One, the compliance procedures would require the opening and repackaging of contents and possible loss of product during distribution and before final sale—a far more expensive technique than checking for compliance by the earlier definition. Two, product packagers would either have to develop and adopt estimates of possible shrinkage and liquid loss in net weight between the times of packaging and final sale, or overpack to assure that the declared net weight was met throughout the rest of the distribution system.

Over 3,000 comments were received on this proposal, with slightly over two-thirds of the respondents opposing it. Seventy-one percent of more than 2,700 comments from individuals objected because they believed that the proposal would over-regulate the industry and increase food costs. Twenty-six percent of the individuals and all but one of the 21 consumer groups supported the proposal. All 31 industry groups which responded opposed the proposal because they believed that there were not sufficient variations for bulk packed items and that it was unclear "who is responsible for short weights at retail."

In order to obtain information on the economic benefits and costs of the proposal not previously determined, and to resolve allegations presented by industry and consumer groups, FSQS awarded a contract for a study to the Consumer Federation of America. The study was completed in October 1978, but failed to reach any conclusive results about the economic benefits and costs.

In the meantime, the House Committee on Agriculture requested the General Accounting Office (GAO) to evaluate the proposed net weight regulation and consider the feasibility of alternative systems. The GAO report, issued on December 20, 1978, concluded that: "Agriculture has not gathered adequate data to determine whether the current system needs to be changed or whether the proposed system or other possible alternative systems would be more economical and practical than the current system." The report also recommended that:

The Secretary of Agriculture direct the Service (FSQS) to expand and extend its search for information concerning the best way to monitor net weight labeling activities for meat and poultry products. Such a search should include:

—a reevaluation of the need for change;

—a comparison of available viable alternatives, including those discussed in this report, the Grocery Manufacturers of America proposal, codex system being developed by the United Nations Codex Committee on Methods of Analysis and Sampling and the so-called "Swedish" method of a declaration on the label of net weight accuracy at the time of packaging;

—a comprehensive economic impact statement for each system considered;

—a thorough and objective analysis of comments from major groups including State and local government regulatory organizations, industry, and consumers affected by such activities; and

—research to resolve the packaged meat and poultry moisture loss controversy.

USDA officials agreed to the GAO recommendation to expand and extend the search for information on the best way to regulate net weight labeling. In January 1979, the Economics, Statistics and Cooperatives Service (ESCS) was asked by FSQS to conduct a study to evaluate the accumulated evidence, reassess the economic costs and benefits, and determine the need for and the economic impact of the 1977 proposal.

The ESCS study concluded that "The proposal would achieve the two objectives defined by FSQS: (1) consumers could be assured that the weight of usable meat and poultry is equal to its labeled weight, and (2) States would be able to enforce strict net weight standards at retail."

However, the ESCS study found that the economic benefits would be much smaller than some consumers had anticipated. A more standardized method of presenting net weight information would be the main benefit to come from adoption of a drained weight system. "Consumers would be better able to make per pound price comparisons."

According to evidence submitted to the USDA hearing clerk, there is already a very high level of compliance—95 to 99 percent—in both dry tare and wet tare States.

The study also found that the information presented about the 1977 proposal had resulted in considerable misunderstanding by both consumers and producers. The study states:

Consumers cannot expect the reported price per pound of a product to remain unchanged if free liquids are excluded from labeled product weights. The price per pound can be expected to increase—and to increase most for those products with relatively more free liquid. However, the cost to consumers for *usable* product would remain unchanged. Actual costs to producers would not increase because of the change in definition of tare (that is, those parts of a product whose weight is not included in the labeled net weight). The amount of drained weight meat would not be affected by a labeling rule, and processing costs per drained weight pound would be unaffected.

Although real costs would not change, consumer misunderstanding could have some long term market effects if they believed that the real price per pound of the products with considerable quantities of free liquid actually increased. They might shift purchases to products that have a lower per pound price. But the problem could be largely corrected by a nationwide education program to explain the reason for the unit price change.

The ESCS study found that application of standards for bulk packed products would be helpful to buyers (other processors or retailers) of these products, especially the small volume ones.

The cost for mandatory quality control was estimated to be between $59 and $116 million, primarily for additional personnel. No cost estimate was provided for an education program to prevent consumer misconceptions about the cause of the unit price changes of affected products. Some retailers might also have experienced added costs to cover the expense of rewrapping products opened for compliance testing.

The ESCS study was submitted for public comment during a 60 day period ending on October 30, 1979. In addition, FSQS mailed out approximately 300 copies to the organizations that had commented on the 1977 proposal. Copies were also distributed to individuals and others who requested the study.

In response to the ESCS study, a total of 101 comments were submitted to FSQS. Again, opposition was expressed to the 1977 proposal. Industry and trade associations almost unanimously preferred the present net weight policy to a drained weight system. Individuals also strongly opposed the net weight proposal, but 14 of the 18 State and local weights and measures regulatory groups expressed support for the proposal. Only one of 51 consumer groups responded.

On the basis of these reviews and studies and the need to resolve the major issues, FSQS has decided to propose a new net weight regulation.

4. *Selection of Proposed Option—Objectives:* These proposed amendments by FSQS to the net weight labeling regulations are designed to: (1) insure that the net weight statement is as accurate as can be expected, on the average, at retail; (2) provide regulatory agencies a standard procedure to enforce net weight standards; and (3) make compliance procedures compatible with those of the Food and Drug Administration to the maximum extent possible.

One might expect that the desirability of a particular net weight regulation would be evaluated in terms of its usefulness to the consumer as a generator of information, its ease of enforcement, and the extent to which it can be used by industry. Unfortunately, evidence concerning the utility to consumers provides little basis for choosing between possible net weight regulations. Likewise, it is not possible to predict industry's responses to various regulations.

Some of the options discussed below eliminate or reduce free liquid from calculation of a product's net weight; however, as the ESCS study shows, the consumer will probably pay the same price for the same amount of usable product under any net weight definition. If revised regulations require producers to alter the labeled net weight on a package, they can be expected to alter correspondingly the price per pound so that they receive the same price for the package as under existing regulations. (If producers incur additional costs to comply with new net weight regulations, the consumer may pay more per pound.)

The ability to compare the cost of different products does not fare much better as a basis for distinguishing between options. Although some options appear to promote packaging that would be more revealing, it is not possible to predict the actual packaging that will result from any option, as the producer's decision involves trade-offs between the cost of packaging materials, the price he is willing to charge for his product, and the appearance he wants to give his packaged product. Under different circumstances, this may produce different combinations of packaging, labeling and price.

The development of a satisfactory net weight regulation which couples ease of compliance, ease of enforcement and compatibility with FDA is reflected in Option B. That option, therefore, is proposed. A summary of the Department's analysis on that basis follows.

5. *The Regulatory Options:* A description of each of the seven options and their impacts upon the main purpose of the regulation are presented below. An assessment of the impacts of each option is also presented.

Option A: Continuation of the present system.

Description: Continuation of the present system would maintain all existing net weight and compliance rules as they are presently interpreted. The net weight label statements on packages of meat and poultry products for household use would be considered in compliance at the time the packages are shipped from the producing establishment and at retail when "reasonable variations" for loss or gain are present. Net weight would, in the majority of cases, continue to be determined by the dry tare definition (total package weight minus the dry weight of all the packaging and labeling materials).

In those instances when the contents have been packaged for a period of time and the packaging material has absorbed considerable moisture, the wet tare definition (total weight of package and contents minus the weight of the packaging materials and absorbed moisture) may be used to check compliance with the stated net weight. Any free liquid in the package would be considered part of the net contents. A reasonable but undefined allowance for variation in net weight would be permitted for moisture gained or lost during good distribution practices or from unavoidable deviations during good manufacturing practice.

Drained weight (total package weight minus the weight of the packaging materials and all free and absorbed liquid) would be used for some products packed in nonusable liquid media. These products, such as Vienna Sausage packed in water, would continue to be checked for compliance by the drained weight method.

For compliance purposes, FSQS inspectors and plant personnel operating a voluntary net weight quality control program under FSQS approval and supervision would continue to verify the stated net weight on packages. In their respective jurisdictions, State and local weight officials would be able to determine compliance of federally inspected packages.

In conducting compliance activities, lots are sampled for net weight determinations. For samples of less than 40 packages per lot, the lot is considered to be in compliance if the average net weight of the sample packages is equal to or greater than the declared net weight and none of the samples are unreasonably below the declared net weight. This means that the net weight of some packages may be less than the stated weight on the label. Also, reasonable allowances for moisture loss or gain can be applied to the measurement if net weight is determined at locations other than the producing plants. In those instances where the sample consists of 40 or more packages per lot, one package with a weight that differs considerably from the label net weight can be excluded from consideration in evaluating the individual container, but is not excluded from the sample average.

Impact of Objectives

Ease of Enforcement: Present FSQS regulations do not include standardized procedures that allow State and local officials to determine compliance of federally

inspected meat and poultry products. Also, because the present regulations lack explicit allowances for "reasonable variations," they restrict the actions of State and local officials in determining whether the net weight of federally inspected meat and poultry products is in compliance.

Net weight quality control programs would remain voluntary. Firms would be allowed to adopt net weight quality control programs to ensure compliance with the regulations.

Accuracy: The total net weight of packages sampled must equal or exceed their labeled net weight and, with the exception noted above for samples of 40 or more packages, none of the packages may be unreasonably below the declared net weight. Present regulations do not, however, specify maximum allowable variation.

Compatibility with FDA: This option does not provide explicit allowable variation for net weight labeling, nor do current sampling procedures conform to those in the new FDA proposal.

Economic Impacts

Consumers: All free liquids (except nonusable liquids) and some liquids absorbed by packaging materials are included in a product's net weight. Consumers may have difficulty comparing values of various packages of product because of the variability in free liquid content.

Industry: Retailers will have to continue to check the weights of bulk shipments of wholesale-size packages for accuracy, because present procedures are not adequate for verifying the accuracy of the net weight declarations.

Regulatory Agencies: FSQS's net weight regulatory and compliance costs currently equal approximately $5.75 million a year. Costs for State and local agencies are not known. Future costs will be affected by increases in hourly wage rates and other cost items.

Distribution of Effects

Conditions will not change.

Option B: The Proposed FSQS Regulation.

Description: This proposal is based on the studies, comments, reviews, analyses and efforts by FSQS and FDA to develop more uniform net weight labeling proposals following publication of the 1973 and 1977 proposals. (See Options C and D.)

The proposed regulation provides that the net weight would equal the gross weight of the package minus the weight of packaging materials. Free liquids that drain from the product would be considered part of the net contents except for the few meat and poultry products to which a non-usable medium is added at the time of packaging. Such medium would not be included in the net weight.

The proposal also sets out two alternatives concerning the treatment of liquid which has separated from the product and is absorbed by the packaging material. The first alternative would exclude the weight of both the packaging materials and liquid absorbed by packaging materials from the product's net weight. The other would exclude only the weight of packaging materials. FSQS has not yet determined which alternative is preferable.

Regardless of the alternative chosen, the proposal would replace the present reasonable variations allowance with numerical allowable variations developed by the National Bureau of Standards which appear to be reasonable when determined by prescribed procedures. The proposal would also give State and local officials specific procedures for determining compliance with net weight requirements. This option, as the 1973 and 1977 proposals, would resolve the enforcement problem encountered by State and local weight officials. However, allowances for moisture evaporation losses would not be developed and adopted since this does not appear to be a serious problem affecting the net weight of meat and poultry products at retail. The Agency could consider this, however, if data to the contrary were submitted by interested parties.

Definitions and sampling procedures adopted by FDA and FSQS in their respective proposals have been made uniform to the maximum extent possible.

The exemption currently allowed for the placement and declaration of the net weight statement for shingle packed bacon would be terminated. Also, more reasonable allowances for the net weight labeling of bulk shipments would be adopted.

Impact on Objectives

Ease of Enforcement: The new proposal would remove the enforcement problems encountered under the existing system (Option A). Establishment of explicit allowable variations and adoption of standardized net weight regulations and sampling procedures would facilitate net weight enforcement by State and local agencies.

Net weight quality control programs would remain voluntary, as at present. This will prevent any disruptions at establishments.

Accuracy: Because of the establishment of explicit allowable variations and sampling procedures, the proposal could insure slightly greater accuracy of net weight labeling than currently exists. The net weight of sampled packages must equal or exceed the labeled net weight. Further, for each package sampled, the proposal stipulates maximum negative deviations from the labeled net weight. For samples of 50 or more packages, if the net weight is in compliance, one package can be excluded from consideration in evaluating the maximum negative deviation.

According to the ESCS study on the 1977 proposal, however, there is already a 95 to 99 percent rate of compliance and therefore only limited improvement in the accuracy of net weight labeling can be expected.

Compatibility with FDA: This option is the only one developed in tandem with FDA to assure the maximum possible compatibility with FDA's recent net weight proposal. Sampling procedures under the FDA and USDA proposals differ because USDA samples continuously and FDA does not, but the procedures offer the same statistical validity.

Economic Impacts

Consumers: As discussed above, the proposal will not significantly improve the accuracy of net weight labels for consumer purchases.

However, adoption of the alternative which excludes liquids absorbed by packaging materials may produce a variety of responses from producers. (Possible producer responses are discussed in the next subsection.) If producers opt to continue using current processing methods and absorbent packaging materials under this alternative, they will have to state a lower net weight because the absorbed liquid will no longer be included in the net weight. The producer can be expected to increase the labeled price per pound accordingly. The end result would be a package with a lower stated net weight, a higher price per pound, but no change in either the total price on the package or the quantity of usable product. This same result would be expected if a drained weight system for net weight compliance (Option D) were instituted.

Increases in labeled prices per pound to account for absorbed liquids would not be great. The ESCS study compared the mean drain, as a percent of labeled weight, among products such as chicken breasts, beef roasts, pork chops, bologna, and ham, among others. Only beef livers had a greater percentage of drain than chicken breasts. (Beef livers are generally packaged in non-absorbent materials—as explained later, products packaged in non-absorbent materials will not be affected by this proposal.) The average drain from chicken breasts equalled 3.95 percent of labeled weight. Assuming that the packaging materials absorbed all liquids from chicken breasts, and assuming an average price of $1 per pound, the labeled price would rise only four cents per pound, and the labeled net weight would decline four percent. All non-poultry products other than beef livers had an average drain of less than one percent of labeled weight.

Although neither the total price of the package nor the quantity of usable product would be affected, the consumer might believe the price had been raised, since the stated price per pound would be higher. The amount of increase, however, would probably be too small to affect consumer demand or the choice between products. Further, consumers could be educated to understand that the real price of the product had not increased.

The ability to compare products is affected by the way in which liquid is controlled in the package. Under the alternative which includes absorbed liquids in net weight, producers have an incentive to use absorbent packaging materials because they improve product appearance, but do not reduce the package's net weight. Producers might choose to eliminate the use of absorbent packaging materials under a net weight system which did not consider absorbed liquids as part of the net contents. This would make is more apparent to the consumer that he/she is paying for some liquid.

Industry: The alternative which includes absorbed liquid in the net weight is similar to the way in which net weight is currently determined and should have little or no impact on producers.

The alternative which excludes liquids absorbed by packaging materials from net weight could have various impacts on the packaging and labeling practices of producers, depending on the quantity of free liquid in their products and whether the products' packaging contains absorbent materials. Producers would be unlikely to change their packaging or labeling practices for products packaged in impervious materials. For such products, the only change in net weight regulations would be elimination of allowances for evaporation and creation of a set of allowable variations to replace the existing reasonable variations allowance.

Under the net weight alternative which excludes absorbed liquids, the main impact will fall on producers of products whose packaging contains absorbent material practicularly products with large quantities of free liquid. (This same line of reasoning would hold if a drained weight definition, in Option D, were implemented.) Poultry products comprise the majority of this class.

It is not possible to predict whether producers will opt to continue using absorbent packaging materials and adjust the labeled price per pound, or if they will alter processing methods to reduce the quantity of free liquids in packages. The producer's behavior under the proposed option depends on his desire to maintain the appearance of the package, the cost of absorbent materials, and his feelings about how real or apparent changes in the price of his product will be accepted by the consumer.

Some States have employed net weight regulation systems which exclude absorbed liquid from net weight. We have only sketchy indications of how producers have reacted in those States. We would like to know if producers in those States have altered their processing methods, eliminated absorbent packaging materials, or adjusted prices. If they have altered processing methods, we would like to know the cost of doing so.

The ultimate impact on producers will depend on consumer behavior. This cannot be predicted with precision, because consumer behavior depends on what kind of adjustments producers make in the packaging price; what these adjustments will be is unknown at the present time. In any case, it appears from the available empirical data that any price changes will be so small as to make significant changes in consumer behavior unlikely.

If the net weight excludes liquids absorbed by packaging materials, processors or distributors who continue to use absorbent materials may experience a minor cost increase for product loss or repackaging as a result of net weight testing for compliance. Some of these packages may need to be opened, which will result in some losses.

Regulatory Agencies: Annual FSQS, State and local operating costs for net weight information will remain the same as as present, except for increases from inflation of wage rates and the cost of other items.

Distribution of Effects

This option would tend to have a greater impact on processors and packagers of products that have a high proportion of free liquid. All state and local agencies would be affected by the adoption of the allowable variation process. Wholesale and retail buyers of bulk shipments would receive improve regulatory support in their ability to receive full net weight on those shipments.

Option C: The 1973 USDA Proposal.

Description: This was the first net weight labeling proposal presented following the District Court decision in *Rath Packing* v. *Becker* in California. The purpose was to bring the rules in conformance with the decision of the court.

As a result of the decision regarding vagueness of the rule on "reasonable variations," explicit allowable variations for packages that could be applied by State and local officials were proposed. Products would be assigned to one of six groups depending upon the product's characteristics and the declared net weight of the contents. As long as the average weight of the samples equaled or exceeded the declared net weight and the difference between the declared net weight and the smaller net weight of the contents of the sample item was less than the allowable variation, the lot would be considered in compliance.

The practice of using voluntary net weight quality control programs and Federal inspectors to check for compliance would be replaced by a mandatory quality control program, monitored by Federal inspectors. Any federally inspected establishment producing immediate containers bearing net weight statements would have to obtain approval for and implement a net weight quality control program.

Sampling procedures were proposed for checking the net weight compliance of lots. These procedures do not conform with the procedures and sampling rates devised by FDA—sample sizes vary; tolerances for allowable variations differ; and the 1973 proposal did not permit one package from a large sample to exceed the maximum deviation from labeled net weight.

Exemptions for net weight label placement and declarations on shingle packed bacon packages were proposed to be terminated. Instead of declared net weight for bulk shipments of product, a count of the number of items in the container could be substituted.

Impact on Objectives

Ease of Enforcement: By providing explicit variations and standard procedures for determining net weight compliance, this option would yield the same ease of enforcement as the proposed option.

Instituting mandatory net weight quality control programs would ease the enforcement burden on Federal meat and poultry product inspectors. This burden would be shifted to processors.

Accuracy: This option would require that no packages are less than the allowable variation. Option B permits one deviantly marked package in a large sample; this option requires all packages in a sample to be within the allowable variation before the sample is judged in compliance. However, there is little room for improvement since compliance rates presently exceed 95 percent.

Compatibility with FDA: This option is not compatible with FDA's proposal—sample sizes vary; tolerances for allowable variations differ; and this option does not permit any packages from a large sample to exceed the maximum negative deviation from net weight.

Economic Impacts

Consumers: Because of the already high level of compliance with net weight labeling regulations, consumers could not expect significantly improved labeling accuracy under this proposal. The marginal improvement in accuracy may provide consumers greater assurance that their purchases are properly labeled.

The net weight system is similar to that under the existing regulations. Therefore, producers are unlikely to alter their production or labeling practices, and consumers should see no noticeable impacts as a result of this definition. Product prices for consumers could rise by as much as one-quarter of a cent per pound as a result of increased producer costs from mandatory quality control programs. This increase would be reflected in the Consumer Price Index. (These costs are discussed below.)

Industry: The net weight system contained in this proposal would not cause producers to alter their production or labeling practices. However, the requirement of a mandatory, plant-operated, quality control program to monitor net weight compliance is likely to increase industry costs. The additional annual cost to the 5,680 plants having to adopt a voluntary quality control program is estimated to be between $56 million and $114 million for personnel, according to the ESCS study. The basis for the cost range is whether small plants hire full or part time quality control personnel.

The mandatory quality control program could increase industry employment between 3,500 and 5,700 persons. This would be true only if plants do not already have personnel conducting net weight checks. The number of quality control technicians hired would depend upon whether the smaller plants hire full or part time personnel.

Regulatory Agencies: Implementation of this option would require FSQS to review and approve mandatory quality control net weight compliance programs for approximately 500 plants currently with voluntary programs and another 5,680 without any programs. One time revisions in rules, and instruction of affected officials and plant personnel would be necessary. No increase in FSQS personnel requirements for program development, approval and instruction of personnel is considered necessary. Approximately 157 FSQS inspector years could be displaced by plant operated quality control programs and would be available for use in other FSQS functions. Cost savings from this program, which could be as much as $3.1 million a year, should more than equal the FSQS implementation and monitoring costs.

This proposal would promote more vigorous enforcement by State and local weights and measures officials.

Distribution of Effects

The impacts of this option should be greater for those establishments packaging a

high proportion of consumer-size packages of meat and poultry products characterized by having large amounts of free liquid. All but 500 of 6,180 federally inspected plants would need to develop and implement approved net weight quality control programs. Wholesalers and retailers dealing in bulk shipments of products would be provided either net weight statements or quantity counts of products in such shipments.

Option D: The 1977 FSQS Proposal.

Description: Under this proposal, net weight compliance would be determined by a drained weight system. In addition to the packaging material, all free and absorbed liquids would be excluded from the net contents. Net contents would be only the weight of the usable product. Net content would continue to be the entire contents for those products where the entire contents are to be consumed. In the case of frozen products, net contents would be the total package weight minus the weight of the packaging materials and adhering ice crystals.

Stated allowances for "reasonable variations" would be permitted. Furthermore, the net weight statement would have to be accurate on the average not only at the packaging establishment but at any point in the distribution system, including the point of final sale.

In order to comply, processors would first have to develop estimates of free liquid build-up and possible unavoidable gains or losses resulting from processing and distribution. They would then have to target fill-weight above declared weight or understate net weight accordingly. Estimates of moisture gain or loss require a one-time expense.

Each federally inspected plant packing consumer size packages would have to establish and gain approval of a mandatory, FSQS-supervised, net weight quality control program.

A lot of prepackaged meat or poultry would be in compliance when the average net weight of the samples drawn from the lot equals or exceeds the labeled net weight at any point in the distribution channel and at final sale. In addition, to be in compliance, the actual net weight of each package sampled would have to be within an explicitly defined allowance of labeled net weight.

The exemption for placement and declaration of the net weight statement on single packed bacon would be eliminated. An exemption for small packages (less than one half ounce) from having a net weight label statement would be extended to poultry products.

Impact on Objectives

Ease of Enforcement: As with the two previous options, this proposal would replace the "reasonable variations" provision with explicit allowable variations for individual packages, and provide standardized procedures for enforcement. This would facilitate enforcement by State and local agencies.

Mandatory net weight quality control programs would ease the enforcement burden on Federal meat and poultry product inspectors. This burden would be shifted to processors.

A drained weight system requires more inspector time to check for compliance. (Some States objected to the proposal because of this.)

Accuracy: Like the two previous options, establishment of explicit allowable variations would insure greater accuracy of net weight labeling than currently exists. But the already high compliance rate leaves little room for significant improvement. This proposal with its drained weight provision would assure consumers that the declared net weight on a label is, on the average, the weight of *usable* product in the package. This would improve consumers' ability to compare products.

Compatibility with FDA: This rule would not conform with the new FDA proposal in terms of the net weight definition or allowable variations.

Economic Impacts

Consumers: Consumers would be assured of net weight statements at the time of purchase which would make comparison of product prices on the basis of *usable* product extremely easy. However, as the ESCS study indicated, the perceived benefits are not as great as the real benefits since the real cost of usable product probably would not change. The unit price and the weight may change, but the total cost for the package probably would not change. Consumers probably anticipate, however, that the total price for the product would be reduced by the current unit price times the weight of the liquid. A major educational effort would possibly be essential to promote the concept and prevent widespread misconceptions about the cause of any unit price changes. A transition period between approval and implementation would appear necessary for the educational effort.

This proposal would alter the traditional price relationships between products that do and do not contain large amounts of liquid. The unit price for tray pack chicken, liver and corned beef products, which customarily contain large amounts of free liquid, would increase relative to the prices for other meat and poultry products. (Relative prices would shift less than four percent. See the section on Economic Impacts: Consumers for Option B).

The mandatory quality control program could increase average meat prices by as much as 0.3 cents a pound, or less than 0.3 percent at retail.

Likewise, the costs for processors to estimate free liquid build-up and possible gains or losses during processing and distribution would likely be passed on to consumers in the form of higher prices. Any additional increase in the stated unit price resulting from the shift to drained weight would be reflected in the Consumer Price Index even though there is not any increase in the "real" or *usable* unit price.

Industry: As discussed under Option B, it is unknown what action processors might take in response to a new net weight system. It is clear that a drained weight system for determining net weight compliance would increase processors' costs. These increased costs would come from the one-time expense of estimating moisture gains or losses. The estimates would be used to adjust fill-weights or labeled net weights.

Processors might also consider freezing products as a means to comply with a drained weight definition of net weight. However, freezing costs an estimated five to six cents per pound. For the proposed option, an estimate was that the shift in relative prices per pound would be less than four cents, and would not require a major capital investment like that needed for freezing equipment. A pronounced consumer preference for fresh meat and poultry products over frozen products also reduces the attractiveness of freezing as an adjustment to this option.

A mandatory quality control program would engender the same costs as in Option C, $59 to $116 million, and increases industry employment between 3,500 and 5,700 people.

Processors, wholesalers and retailers would experience minor losses from routine inspections for net weight compliance, which require opening, weighing, and repackaging products.

Wholesale and retail buyers of bulk package shipments would receive more regulatory support for assuring net weight statements on those bulk shipments.

Regulatory Agencies: Again, the impacts of a mandatory quality control program would equal those under Option C. Approximately 157 FSQS inspector years could be made available for use in FSQS functions other than net weight monitoring. Federal cost savings could run as high as $3.1 million per year, and should at least equal all of FSQS's implementation and monitoring costs.

A drained weight system would require State and local agencies to make a one-time expenditure of $420,000 for testing equipment. Some agencies have expressed concern that a drained weight system would take more of their inspectors' time and sap their enforcement capabilities.

Distribution of Effects

All meat and poultry establishments, distributors and retailers, State and local net weight enforcement agencies, and any importers of prepackaged consumer products would be affected by this option.

Option E: Grocery Manufacturer's of America (GMA) Proposal.

Description: In February of 1978, GMA petitioned FDA and FSQS to establish a nationwide program to assure consumers of the accuracy of net weight labels on prepackaged foods. The program, the National Net Weight Assurance Program (NNWAP), would be comprised of government, industry and general public representatives.

The petition further requested retention of the present Federal net weight regulations with several modifications. These are "particularizing" the presently undefined allowances for reasonable variation and adoption of the revised National Bureau of Standards (NBS) Handbook 67, *Checking Prepackaged Commodities* (draft dated December 1977 and modified by memos dated August 1978) for establishing uniform sampling techniques and methods of calculating net weight.

Lastly, the petition requested establishment of a National Net Weight Assurance

Conference. The Conference would oversee the NNWAP, foster net weight compliance through periodic inspection at the time of packaging, and develop procedures for a cooperative inspection program which includes exchange of enforcement data between Federal and State agencies. The Conference would also identify food products subject to moisture gain or loss, estimate their typical moisture content at the time of packaging, and estimate moisture losses through evaporation or moisture gains through absorption while the product is in the food distribution channel prior to purchase by the consumer. These data would be published and used as norms for testing net weight compliance.

Packages of a product would be weighed at retail, or elsewhere, to check the net weight for compliance. If the sample is not in compliance, packages would be collected and sent to designated laboratories to determine the cause of the non-compliance. In the meantime, a hold would be placed on further distribution and sale of the lot or lots sampled. If the tests revealed that the non-compliance is a result of a change in moisture content, and this change were within the established limits of variation, the hold order would be lifted and the lot could be sold.

Determination of tare would vary depending on the product. The petition did not address quality control programs or the disposition of existing exemptions for bacon and bulk shipments.

The enforcement agencies would have concurrent responsibility for determining net weight compliance at the several levels of the food distribution system, in accordance with the draft NBS handbook.

Impact on Objectives

Ease of Enforcement: Maximum allowable variations would be determined on a product-by-product basis. Improved coordination and exchange of data among enforcement agencies could improve the level of net weight compliance.

This option might prove difficult to adopt for checking compliance of highly perishable products—most fresh meat and poultry products fall in this category—because of the potential for large product losses through spoilage. (See below, "Economic Impacts.")

No mention is made of quality control programs, which presumably would remain voluntary.

Accuracy: Within the narrow range available for improving compliance with net weight regulations, more easily enforceable standards should improve the accuracy of net weight labeling.

Compatibility with FDA: This rule would not conform to the FDA proposal.

Economic Impacts

Consumers: The proposal has not been developed to the point where it can be evaluated in great detail. The initial investment for this option could be quite large, resulting in higher product prices. Since it would require 2 to 4 years to implement, consumers would not see any costs or benefits for some time.

Industry: If establishments are responsible for identifying and estimating the moisture losses or gains from their products, the one-time laboratory cost for developing the maximum allowable variations could be significant. Organizational and operating costs of the conference are likely to be insignificant to the individual firms.

The proposal is intended to resolve net weight problems common to dry foods such as flour. The net weight of these products is likely to change considerably because of changes in humidity. Furthermore, the products are not likely to deteriorate into an inedible state while the testing for compliance takes place. Compliance testing could take days for shipping samples to a lab, testing and returning results to the proper authorities.

Packaged meat and poultry products which are generally highly perishable do not usually experience significant changes in weight from loss or gain of moisture. Other meat and poultry products may be canned or packed in impervious type materials that prevent loss or gain of moisture. The type of processing or packaging used on some products might extend the shelf life considerably. But, for the majority of the meat and poultry products, lots subject to compliance testing would spoil, causing large economic losses before test results could be obtained and products released for sale.

Regulatory Agencies: There are no data available on the specific allocation of resources needed for the operation of the GMA proposal. Consequently, it is premature to estimate how many USDA and other Federal resources might be needed. The cost impact might be minor if FSQS and other Federal involvement is limited to conference participation, assisting in coordination of data collection, and review and revision of rules. Operation of labs for enforcement purposes might increase costs considerably.

State and local agencies' responsibilities and procedures for implementing the GMA proposal have not been completely defined. The program could provide cost savings to State and local enforcement agencies once explicit allowances for variation are adopted. They would expedite the compliance testing process, thus increasing efficiency and reducing costs.

Distribution of Effects

No real impacts are likely to occur for 2 to 4 years while implementation plans are being developed.

Option F: Codex System.

Description: The Codex Alimentarius Commission of the United Nations has been in the process of developing procedures for enforcing net weights in prepackaged foods on an international basis. The working committee has proposed that net weight compliance be based on the average net weight of packages at the time of packaging with reasonable tolerances allowed for difficulty in filling containers or maintaining net weight while in distribution.

Sampling for net weight compliance would be modeled on a statistical limits of variance technique developed by Switzerland for application to imported, prepackaged foods. Inspectors would make limited inspections for compliance at retail. If the sampling technique indicates a noncompliance problem, additional inspection of the same product would be made at retail and further back in the marketing chain, including at processing plants. If the problem continues following notification of the producers, a more precise enforcement test would be applied.

This building-block approach would assure a high probability of net weight compliance, but not necessarily as high as the current level found in the United States. It would require application of a relatively sophisticated sampling technique and a well coordinated Federal, State and local enforcement effort. This coordination effort would be essentially the same as the one contained in the GMA proposal.

To date, the Codex Committee, which is made up of representatives from many countries including the United States, has not formally voted to accept recommendations on any of the standards and procedures. At the most recent Committee meeting, it was voted to have the proposal referred back to the working group for further study. The United States is on record as opposing the building block concept because it would require at least two-thirds of all the sample packages drawn from a lot to have a net weight of contents equal to or in excess of the amount stated on the label. This would require processors to either overfill containers or reduce the net weight stated on the label. In either case, the labeled unit price for the contents would have to be increased. As previously discussed, this would not change the price per usable pound of product.

The United States position is to continue generally the present practice of having the average net weight of the samples drawn from a lot equal to or exceeding the labeled net weight. This proposal does not stipulate what proportion of a lot should exceed the weight requirement. But, on average, about half of the items in the sample would have net weights equal to or exceeding that stated on the label.

Impact on Objectives

Ease of Enforcement: This option could reduce the effectiveness of enforcement at retail and other points in the distribution channel beyond the processor. It concentrates on net weight compliance at the time of packaging and is supplemented by limited inspections for compliance at retail. Determination of compliance is based on the average net weight of packages, allowing reasonable tolerances for individual packages, but in this case it does not imply increased accuracy for the consumer.

Weight: Because the system emphasizes compliance at the time of packaging, it could reduce accuracy at retail. On the other hand, the option requires at least two-thirds of all sample packages to have a net weight at least equal to the labeled net weight at the time of packaging. This second requirement would tend to support the already high level of compliance, especially for meat and poultry products, which have little problem with moisture loss through evaporation.

Compatibility with FDA: This option represents a major departure from both the current method of enforcing net weight regulations and the FDA proposal.

Economic Impacts

Consumers: The proposal is not expected to create many changes for consumers. According to the ESCS study, if producers must overpack to comply with the regulations, consumers might see shifts in relative prices, but no change in the price of usable product.

Industry: Producers might have to overpack, or change the labeled price per pound and the stated net weight on their products. This should not result in any significant costs. Lack of any specific information on what standards and procedures might be recommended prevents an assessment of other economic impacts.

Regulatory Agencies: Lack of any approved recommendations on how the standards, procedures, and the Codex proposal might be organized and operated make it premature to estimate the cost impact. Adoption of new rules and a different sampling technique should result in an unknown cost increase for FSQS. Implementation of the building-block concept and use of a more sophisticated statistical verification technique would tend to increase enforcement training and operating costs.

Distribution of Effects

No impacts would occur until the Codex Committee agrees on recommendations and they are adopted by the United States. It is unlikely that this will occur for several years or more.

Option G: Declaration of New Weight at Time of Pack—"Swedish" Method

Description: This option is used in a number of countries including Canada and Sweden. It requires a qualifying phrase on packages that states that the net weight was accurate at the time the food was packaged at an establishment.

Impact on Objectives

Ease of Enforcement: This option would not facilitate State and local net weight enforcement unless the rule allowing for reasonable variation is eliminated.

Accuracy: Since meat and poultry products could be packaged some time before and some distance from the point of purchase by a consumer, the net weight of the contents at the time of final purchase might differ from the declared weight at the time of pack. However, this has not been a significant problem under the present system and would not be expected to become a problem under this option.

Compatibility with FDA: This option adopts none of the sampling procedures or enforcement standards contained in the new FDA proposal.

Economic Impacts

Consumers: There would be no impact on consumers.

Industry: Establishments would incur a one-time cost to have packaging material manufacturers add the appropriate qualifying statement.

Distribution of Effects

The impact should be limited to establishments packing consumer size packages of food.

Summary

This section summarizes the extent to which each of the proposed options meets the objectives outlined in Section 4 above.

Accuracy: Options B, C, D, E, and F make explicit the amount by which individual packages can deviate from the stated net weight when they are checked for net weight compliance. These explicit allowances are an improvement over Option A, the current system, which allows "reasonable variations." Option C, the 1973 proposal, contains the most strict standard for enforcement; it does not permit any deviantly labeled packages in large samples, as do Options B and D. Options E and F, the GMA and Codex proposals, do not contain standardized net weight regulations and sampling procedures, and therefore do not improve the enforceability of the net weight label requirements.

Standardized Enforcement Procedures: The explicit allowances discussed above and the provision of specific sampling procedures on Options B, C, and D, increase the ability of State and local agencies to enforce net weight regulations and should help raise the already high level of compliance. Options E and F do not meet this objective since they do not contain standardized net weight regulations and sampling procedures.

Compatibility with FDA: Option B is the only option compatible with FDA's net weight proposal.

Thus, on the basis of the three objectives we have in proposing new net weight regulations, Option B would be most effective. It is essential, however, to review more closely the impacts of Option B to assure that its benefits are not vitiated by relatively less desirable impacts *vis a vis* the other options.

As we mentioned in Section 4, improved net weight regulations can benefit consumers in two ways; first, they should reflect the cost of a unit of usable product; second, they should help the consumer compare the cost of different products.

The analysis of the seven options indicates that none of the options would greatly increase the benefits of the first kind to the consumer. Over 95 percent of meat and poultry packages are currently in compliance with net weight labeling regulations. Explicit allowances and standardized enforcement procedures can improve upon this slightly. On this basis we can choose Options B, C, or D over A, E, F, or G.

As this analysis has stressed, it is likely that no system of net weight regulation represented by Options B, C, or D would change the *real* price per pound of usable product. Thus, Option B is at least as good as C or D with respect to the value the consumer gets for his/her money.

Option B, the 1977 proposal with its drained weight system, would make it easiest for consumers to compare the price per pound of usable product. The proposed option, Option B, using the alternative which excludes liquids absorbed by packaging materials from net contents, would also facilitate comparison of products. Consumers would be able to observe the amount of free liquid for which they are paying. It is difficult to support any particular net weight system on the basis of the information it provides to the consumer, since for practical purposes, comparisons across products would still be very difficult to make under any definition. However, package-by-package comparisons within products would be made easier. The issue in choosing between the alternatives under Option B is whether this increased ease of comparison within products is worth the chance of confusion from changes in labeled prices. Although education could help eliminate this confusion, it has a cost.

As far as raising producer costs are concerned, Option B should not increase producers' costs under either alternative. No options will decrease processors' costs. Options D could raise processors' costs not only because of the mandatory net weight quality control program, but also because a drained weight system would require processors to change processing methods and/or incur added costs to adopt procedures for correct labeling under this system.

Option D also has the disadvantage of increasing enforcement costs because of a one-time expenditure of $420,000 for test equipment and because of a requirement for more inspectors' time in the enforcement procedure.

Thus, considering both its effectiveness in meeting the stated objectives and the avoidance of undesirable impacts, Option B was selected over the other options because:

—It promotes easy enforcement of net weight regulations by state and local agencies.

—It would generate net weight statement at least comparably accurate to all other options, and would establish numerically allowable variations which are not present in existing regulations.

—It would not force processors to increase expenses to comply.

—It is the only option compatible with FDA's net weight proposal.

—It would not increase the costs for regulatory agencies.

6. *Public Comment:* Interested persons will be invited to submit comments concerning the proposed action. All submitted comments will be available for public inspection. A 90 day comment period will be provided.

Dated: August 1, 1980.

Approval:

Susan Sechler,

Deputy Director, Economics, Policy Analysis and Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 79N-0292]

Food Labeling; Net Weight Labeling Requirements

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing amendments to the net weight labeling regulations. These amendments would quantitatively define permissible "reasonable variations" from stated net weights for several food categories, including foods subject to moisture loss. This proposal is prompted by petitions and requests and public hearings conducted by FDA and the U.S. Department of Agriculture (USDA) and would provide a basis for more effective enforcement of the net weight labeling regulations.

DATES: Written comments by November 6, 1980. The agency proposes that the final regulation based on this proposal be made effective 90 days after date of publication of the final regulation in the Federal Register.

ADDRESS: Written comments (preferably four copies) to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Howard N. Pippin, Bureau of Foods (HFF–312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–245–3092.

SUPPLEMENTARY INFORMATION:

Legislative History and Judicial Background of Net Weight Regulations

Section 403(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(e)(2)) states that a food shall be deemed to be misbranded if the package does not bear a label containing "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided,* That under clause (2) of this paragraph reasonable variations shall be permitted, * * *." The existing regulation concerning net weight labeling of human foods (21 CFR 101.105(q)) states: "The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large."

Many foods contain appreciable amounts of water and thus are subject to weight loss due to water evaporation after packaging. The extent of evaporation depends on the inherent characteristics of the food, the packaging materials, and the conditions of food storage, including such factors as humidity, temperature, and duration of storage. Concern for this water loss, coupled with the practically impossible task of packaging to exact weights, prompted Congress to address the issue of net weight labeling of food products at least as early as March 3, 1913, when an amendment to the Pure Food and Drugs Act of 1906 was enacted. The amendment allowed for slight changes in exact quantity of contents due to natural causes. It provided "that reasonable variations shall be permitted, * * * by rules and regulations." Federal regulations adopted in 1914 further addressed the question of net weight labeling and variations due to moisture loss:

> (i) The following tolerances and variances from the quantity of the contents marked on the package shall be allowed:
>
> (1) Discrepancies due exclusively to errors in weighing, measuring, or counting which occur in packing conducted in compliance with good commercial practice.
>
> * * * * *
>
> (3) Discrepancies in weight or measure, due exclusively to differences in atmospheric conditions in various places, and which unavoidably result from the ordinary and customary exposure of the packages to evaporation or to the absorption of water.
>
> Discrepancies under classes (1) * * * of this paragraph shall be as often above as below the marked quantity. The reasonableness of discrepancies under class (3) of this paragraph will be determined on the facts in each case.

The concept of "reasonable variations" in net weight labeling was thus recognized by statute as early as 1913 and by regulations as early as 1914. These regulations were sustained by the courts in 1932 (*United States* v. *Shreveport Grain and E. Co.,* 287 U.S. 77(1932)).

When it passed the Federal Food, Drug, and Cosmetic Act in 1938, Congress retained much of the earlier language concerning reasonable variations from the declared label weight, measure, or numerical count (21 U.S.C 343(e)).

The Fair Packaging and Labeling Act (FPLA) of 1966 also addressed the concept of an allowance for reasonable variations from the declared net quantities of food. In Congressional consideration of the FPLA, the question of unavoidable variations due to moisture loss or mechanical deviations was specifically raised. During the hearings conducted by the House of Representatives Committee on Interstate and Foreign Commerce before drafting the FPLA, no change from the earlier position of reasonable variations was recommended. The FPLA states that "The net quantity of contents (in terms of weight * * *) shall be separately and accurately stated in a uniform location upon the principal display panel of the label" (15 U.S.C. 1453(a)(2)). It further states: "Nothing contained in this chapter shall be construed to repeal, invalidate or supersede * * * the Federal Food, Drug, and Cosmetic Act" (15 U.S.C. 1460). Congress again had the opportunity to modify or eliminate the allowance for reasonable variations due to moisture loss that is permitted by the Federal Food, Drug, and Cosmetic Act, but chose instead to retain it unchanged.

In the Supreme Court case of *Jones* v. *The Rath Packing Co.,* 430 U.S. 519 (1977), the situation addressed by the Court was that the Federal regulations on net weight lableing allowed for reasonable variations due to moisture loss, while California law made no allowance for loss of weight (moisture) during good distribution practice and required instead a minimum weight at the retail store. The Court held that State regulations, when in conflict with or substantially different from Federal regulations, were preempted by Federal law.

In summary, the intent of Congress to allow "reasonable variations" in the net weight labeling of foods due to unavoidable moisture loss is apparent from the amended version of the Federal Food and Drugs Act of 1906, in the reenactment of the Federal Food, Drug, and Cosmetic Act in 1938, and in the FPLA of 1966. Because Congress passed the newer statutes in substantially the same form as the earlier version, it is presumed to have adopted the prior judicial construction of the language.

Petitions Proposing Modifications in Existing Regulations

The California Department of Food and Agriculture, initially with support from officials of 48 States (the number is now fewer than 48), numerous farm and consumer organizations, and many weights and measures officials, petitioned the FDA, USDA, and Federal Trade Commission to amend the existing Federal regulations (21 CFR 101.105(q), 21 CFR 501.105(q), 9 CFR 317.2(h)(2) and 16 CFR 500.22) concerning net weight labeling of packaged foods. The petitioner and supporters assert that the Federal net weight labeling regulations are unfair to consumers because they do not receive full measure as represented on the package. It is also asserted that these regulations preclude enforcement by State and local officials at the retail level because the phrase "reasonable variations" is undefined and vague. The petitioners propose to require a minimum declared weight, suggesting either overfilling to compensate for moisture loss or improving the food

packaging to impede moisture loss to ensure a minimum weight of food at any point during distribution, that is, at the retail level. The petitioners contend that industry has the capability to evaluate all the variables affecting moisture loss for their products and industry can, therefore, adjust the processing and target weights accordingly to minimize excessive overfilling. On several occasions, supporters of the California petition indicated that the Federal regulations should be amended by defining the phrase "reasonable variations" to facilitate enforcement.

Those who favor retaining an allowance for "reasonable variations" due to moisture loss support the petition submitted subsequently by the Grocery Manufacturers of America, Inc. (GMA) to FDA (Docket No. 78P–0040) and USDA. GMA asserts that the existing Federal regulations are not only reasonable, but essential. GMA maintains that no chronic short-weight problems have existed for approximately a decade, thereby illustrating the enforcement effectiveness of the present regulations. Where moisture loss can affect weight, GMA contends that the consumer is getting full value based on the nutritional food "solids." Industry representatives state that moisture loss occurring during distribution and storage is beyond the manufacturer's control. GMA maintains that the modifications proposed in the California petition—overfilling and improved food packaging—would provide no consumer advantage and would cause higher food costs. Instead, GMA recommends creating a National Net Weight Assurance Program to (1) establish a list of foods subject to moisture gain or loss, together with a normal moisture range at time of packaging; (2) foster the determination of net weight compliance of products through periodic inspections at the time of packaging; and (3) develop procedures for establishing a cooperative inspection program and for exchanging enforcement data between States and the Federal Government. GMA further encourages conducting net weight labeling inspections in accordance with the statistical sampling procedures described in the final draft of the revision of the National Bureau of Standards Handbook 67, "Checking Prepackaged Commodities" dated December 1977. The GMA proposal has received widespread support from the food industry.

Coordination of FDA and USDA Proposals

Following the 1977 Supreme Court decision in the *Rath* case, the merits of a parallel FDA/USDA net weight proposal were considered. In the Federal Register of October 14, 1977 (42 FR 55227), a notice was published announcing public hearings to be held jointly by FDA and USDA regarding possible modifications of the current regulations on net weight labeling of products. Legislative-type public hearings were held in San Francisco, CA, on December 8, 1977, and in Atlanta, GA, on December 15, 1977. Interested persons were invited to present their views orally or in writing. Representatives from numerous State and local governments, weights and measures associations, consumer groups, and various industries responded by providing information and views. These submissions from various sources were thoroughly reviewed, and the germane information obtained from the comments and testimony has been incorporated throughout this preamble. Transcripts of the hearings and all written comments and communications concerning the net weight regulations have been placed on public display in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

At the same time, to fill the void left in State compliance programs by the Supreme Court decision, USDA published its net weight labeling proposal in December 1977. During the past several months there have been continued efforts between FDA and USDA to coordinate the net weight proposals. Concerted efforts were made to develop respective documents that were identical, when possible, or at least were mutually compatible. Because of basic differences in the characteristics of the food products regulated by the respective agencies, however, some differences in the proposals remain.

Net Weight Labeling Issues

The issues regarding the net weight labeling regulations can be grouped into two categories: (1) consumer protection from short-weight practices and (2) enforcement of the regulations.

Analysis of Consumer Claims of Short-Weight Practices

Examination of State and nationwide surveys on actual versus declared net weight from 1959 through mid-1977 indicates that no chronic short-weight problem for food commodities has existed for approximately a decade. On the average, consumers receive more than the labeled weight of foods.

In 1959, FDA conducted a nationwide check on the net weights of 36 different packaged foods and determined that 6 percent were short-weight in excess of 1 percent. In 1971, FDA again initiated a survey to establish the level of compliance with the Fair Packaging and Labeling Act and contracted with 11 States to conduct such a study. The findings revealed that approximately 7 percent of the products were apparently 1 percent or more short-weight. The reliability of these results was questioned because of the small data base considered. A followup nationwide net weight survey of dry packaged foods was conducted in 1973, using a larger data base. Only 0.7 percent of the dry-packaged food sampled were found to be short-weight by more than 1 percent. Various retail sampling programs were conducted from 1973 through 1975 to obtain a statistical profile of several product characteristics, including net weights. Overall the average net weight to declared label weight ratio exceeded 1.00 for all products considered. The ratios ranged from 1.02 to 1.08, with the average value of 1.04, signifying that packages, on the average, were overfilled by 4 percent.

The California Department of Food and Agriculture reported that its inspections during 1976 showed that over 97 percent of all food products were full-weight at the time of local inspections, and that milled products were 96 percent accurate. In checking over 40,000 lots of packaged commodities every year, Pennsylvania officials reported that 95 percent of all standard-packed commodities met or exceeded the net weight requirement under the lot averaging concept. Of the remaining 5 percent, 10 percent (that is, 0.5 percent of all products inspected) were short-weight by more than 1 percent of the labeled weight. Of the packages checked by Virginia officials during the year ending June 30, 1977, 7 percent were ordered off-sale because they did not contain the full stated weight. The Maryland Department of Agriculture reported that its compliance level was 89 percent. Although the Virginia and Maryland figures indicate slightly lower levels of compliance with their respective net weight regulations, no further breakdown was provided that might reveal the extent to which packaged foods were short-weight or the prevailing conditions of the packaged foods. Consequently, it is difficult to interpret further the significance of the Virginia and Maryland surveys.

The evidence gathered at both State and national levels fails to substantiate the claim that consumers have been subjected to sustained or intentional short-weighting. On the contrary, the most recent nationwide survey reveals

that consumers routinely receive a 4 percent overfill for the average of all packaged foods purchased.

Two factors, technological developments and government enforcement practices, are primarily responsible for the observed high levels of compliance with the net weight regulations.

Most large industries use sophisticated automatic filling machinery capable of packaging large volumes of foods quickly and within fairly narrow tolerances of the desired target weights. High-speed check-weighing equipment is also available to serve as a safeguard against overfilling and underfilling packages outside of the preselected weight range. When a sufficiently large volume of packages is considered, actual package weights normally cluster closely about the target weight. This fact viewed statistically further aids industry in selecting target values that result in the high compliance rates observed.

It should be noted that bulk-packed foods, whether packaged for wholesale or consumer distribution, are also subject to the net weight labeling regulations.

The FDA and State and local agencies have long worked together to enforce the accuracy of quantity of contents declarations that appear on packaged food labels. FDA has generally focused its efforts of enforcement of the Federal Food, Drug, and Cosmetic Act (the act) and FPLA on plants where foods are packaged. FDA has taken the position that packaged foods entering interstate commerce must contain quantities of food equal to or greater than the weights declared on the labels. State and local agencies traditionally enforce quantity of contents requirements in food establishments where food is offered for retail sale. Enforcement of the net weight regulations is more comprehensive at the State and local levels because of the continual policing of retail establishments by State and local agencies. It is the combined ongoing surveillance by Federal, State, and local agencies that encourages businesses to comply with the regulations.

Enforcement of the Regulations

The *Jones* v. *The Rath Packing Co.* Supreme Court decision brought into focus a very real problem for State and local officials who attempt to enforce net weight labeling regulations at the retail level. The inspector must address the question of whether or not moisture loss may be the basis for the weight shortages detected and, if so, whether the extent of mositure loss is "reasonable." Even though FDA has available some information that could provide guidance concerning selected foods under limited conditions, the inspector must resort to making judgments as to what is "reasonable." Because the regulations have not quantitatively defined "reasonable variations," a difficult burden is placed on inspectors who further recognize that their judgments may very well be challenged and overturned in court.

The actual means of inspecting packages for compliance also presents a problem for inspectors. One accurate method that has been applied to flour involves performing laboratory analysis of the retail product for water content and calculating the hypothetical weight of the product at a designated moisture content. This approach is, however, very cumbersome, time consuming, and costly. Most State and local enforcement officials prefer the convenience and uniformity of accurate scales that they can use in the retail stores to determine product weights without having to rely on laboratory analyses for theoretical weights.

Adopting amendments to the Federal net weight labeling regulations that minimize inspectors' subjective and speculative judgment clearly would be the approach preferred by State and local enforcement officials.

Economic Aspects of California Proposal

If a minimum weight standard at the retail level were established as requested by the California petitioners, industry asserts that it would have to implement modifications in the food-packaging operations that would be inflationary because the associated costs of these modifications would ultimately be passed on to consumers in the form of higher food costs. Industry maintains that these increased costs may negate the consumer benefits to be derived from the assurance of a minimum weight.

To ensure a minimum weight in the packaged foods, industry could, as the California petitioners request, increase target weights, thereby overfilling most packages. Options that do not provide additional weight are available as well. Food producers could alter food-packaging materials to prevent or retard moisture loss, or they could incorporate more sophisticated machinery to deliver more exact weights with reduced deviations.

Overfilling Packages

Based on a University of California study on 689 lots of food, target weights must be adjusted to 109 percent of the declared label weight (that is, a 9 percent overfill) to reduce the probability of underweight packages to 0.1 percent. Considering the $93.8 billion spent in 1976 on foods subject to moisture loss, assuming a 4 percent overfill to allow for moisture loss, and further assuming that a 4 percent overfill translates into a 4 percent cost increase, GMA estimated that consumers would have to bear the burden of $4 billion in addeds cost. If the overfill were to stimulate only a 2 percent cost increase, the added cost to consumers would be about $2 billion.

The Millers' National Federation estimates that the level of overpack required to accommodate the position advocated by the California petitioners lies in the 5 to 6 percent range. Congressman Don Edwards from the 10th District of California indicated that an error level of 5 percent on each packaged food would result in an extra charge to consumers totaling $1 billion annually.

The economic consequences of overfilling food packages have been addressed during the deliberations with USDA. The costs associated with industry operations and passed on to consumers were considered, as was the consumer perception of the costs as a consequence of the proposed regulation.

Some argue that overfilling a food package while increasing the package cost to compensate does not increase industry's costs, nor would consumers' "real" costs on a per-weight basis increase. In effect, consumers gain additional food for the additional expense.

Nevertheless, increasing the package price while providing an increased quantity of food and leaving the declared label weight on the package unchanged may result in the consumer perception of an apparent increase in the cost of their food. This may generate some confusion in the marketplace. While overfilling would eliminate underweight packages, this practice, in turn, would impede the consumers' ability to make value comparisons among different brands of a given food item. Although identical products packaged by different firms would, in all likelihood, contain the required minimum content of food, the amount of overfill may vary markedly. Thus, a consumer would be unable to make a value comparison based solely on examination of labels.

The claim made that overfilling of packages would be inflationary has been carefully evaluated. FDA and USDA concur that the projected inflation resulting from overfilling as described by industry has been overstated. Nonetheless, a slight but real

additional cost could result from the overfilling approach for some products requiring machinery modifications (see below).

Equipment Modifications

Buying new equipment that can provide greater assurance of compliance with the regulations is another option available to industry. More sophisticated filling machinery that delivers food with increased accuracy, or check-weighing equipment, which automatically weights each package after filling to ensure a minimum content, is available. In either case the expense of purchasing new equipment would be passed to the consumer. The consumer does not necessarily receive additional product, but rather pays for the added assurance that the product is probably not short-weight.

Modification of Packaging Materials

Packaging foods in hermetically sealed containers may be an effective approach in reducing moisture loss for many foods, but several large-volume commodities develop less desirable characteristics when not allowed to "breathe." Flour and rice deteriorate more quickly when stored in air-tight containers. Certain cheeses must be packaged to minimize moisture loss while allowing continued aerobic curing. Moisture must be allowed to escape from baked goods such as bread, pies, and glazed doughnuts to prevent these foods from becoming soggy.

Paper or cardboard packaging now constitutes about 5 to 10 percent of a dry product's retail cost. Depending on the product, GMA stated that introducing a moisture barrier would increase packaging costs by 80 to 90 percent. The Millers' National Federation noted that the packaging for a 5-pound bag of flour costs 2.75 cents. By including a moisture barrier, each package would cost 4.85 cents. However, the lack of porosity in these moisture-proof bags and the resultant air entrapment reduces the packing-line efficiency now available with high-speed machinery. Were a can to be used to package flour, the Millers' National Federation said the package cost would escalate to between 36 and 50 cents a can. GMA reported comparable figures for packaged flour. The American Frozen Food Institute estimated that adding moistureproof barriers would stimulate a 3 to 4 percent cost increase per package, and the Dried Fruit Association of California said there are no economical dried fruit packaging materials that can prevent moisture loss or gain.

The proposed widespread use of moisture barriers presents additional problems of national concern. A heavier reliance on moisture barriers would result in the expanded use of nonrenewable fossil-derived energy sources, and since the moisture barriers are generally not biodegradable, the disposal of spent packages would create an additional environmental burden.

Each of the options discussed above introduces additional cost that must be borne by the consumer. However, certain industries have pointed out that the consequences of increased food costs may be selectively detrimental to firms such as those dealing with seafood and other frozen foods. Because seafood products are more expensive than many other foods, further price increases may drive consumers to seek less expensive alternatives. Similarly they contend that consumers may switch away from frozen foods to other packages not susceptible to moisture loss, for example, canned goods, rather than absorb a price increase.

Uniform Net Weight Standards

Current Federal net weight labeling standards, which allow for "reasonable variations," are less stringent than some State net weight regulations. Since the Supreme Court decision in *Jones* v. *Rath* affirmed the preemptive status of the Federal regulations, packaged foods entering into interstate commerce that are subject to inspection must be examined in accordance with Federal regulations.

Were the Federal regulations amended to require a minimum declared weight as suggested in the California proposal, intrastate businesses could have an economic advantage over interstate firms. Those industries engaged in interstate commerce must pack for more diverse conditions and, consequently, would have to either overpack (assuming extreme conditions of moisture loss) or custom pack (for different geographic regions). Industries serving less diverse climates would have more controlled environmental conditions to contend with and would be able to project moisture losses more accurately, thereby incurring less expense.

Regardless of whether current or amended Federal net weight regulations prevail, those manufactured and packagers involved in intrastate distribution of packaged foods are not subject to Federal regulations, but they must comply with the State regulations. Where the State net weight regulations are more stringent than the Federal regulations, intrastate businesses may be at an economic disadvantage. However, this potential inequity must be resolved by the individual States because no authority exists for FDA intervention in intrastate activities of this type.

Compliance with net weight labeling regulations by most manufacturers and packagers, regardless of ultimate location of the market, can be better achieved by amending the Federal regulations. This conclusion is discussed below.

Proposal

None of the alternatives advocated by the California petition would provide any consumer benefit without introducing disadvantages such as inflation or reduction in the consumers' ability to make value comparisons. The proposal submitted by GMA to establish a National Net Weight Assurance Program and to further develop a cooperative inspection program is not without merit but the mechanism GMA proposes is a cumbersome way of achieving what FDA believes can be accomplished very simply.

Therefore, FDA concludes that the deficiencies in the net weight labeling regulations, as delineated in the foregoing discussion, can be resolved by amending the regulations: (1) to adopt standardized methods and uniform procedures for assessing compliance of packaged foods with the net weight labeling regulations, and (2) to identify those foods subject to moisture loss, classifying them by food category and quantitatively specifying the maximum acceptable levels of moisture loss for each of the food categories.

Procedures

Because State and local inspection procedures can vary appreciably from one location to another during the evaluation of packaged foods for adherence to 21 CFR 101.105(q), there is a need to standardize techniques and methods of sampling and measuring to be employed during the sample examinations. Consequently, FDA, in collaboration with USDA and after technical consultation with the National Bureau of Standards (NBS), proposes to adopt with some modifications the sampling methodology identified as Sampling Category B in the final draft of the revision of National Bureau of Standards Handbook 67, "Checking Prepackaged Commodities," dated December 1977 and modified by memorandum in August 1978. This working draft will soon be superseded by new NBS Handbook 133, "Checking the Net Contents of Packaged Goods," which is not yet published. Numerous comments were received from weights and measures officials and industry

representatives alike in support of the use of NBS Handbook 67.

Identifying the types of tare weights and explicitly defining what is meant by the terms are fundamental aspects of this net weight labeling proposal.

The tare weight has been defined for nonfrozen food products as the weight of the package materials, including adhesives, labels, ties, etc., and the weight of any adhering or absorbed juices, fats, or solids that would normally not be consumed. Any large portions of food adhering to the package materials during the tare weight assessment are to be removed from the package in a manner consistent with usual consumer practices.

The tare weight for frozen food products includes both the weight of the container and any adhering ice crystals.

Certain frozen foods, such as shrimp, are coated by the addition of water or other externally applied solutions just after freezing in order to form a glaze. During frozen storage, this added glaze serves to protect the product from storage-related deterioration. The tare weight for these frozen food products includes the weight of the container and any water or solution added as a glaze. It should be emphasized that the glaze added to these products is not intended for consumption; it serves a specific technological effect in the food.

As previously described in the November 7, 1975 **Federal Register** proposal pertaining to drained weight (40 FR 52172), "* * * it has been the policy of the FDA to regard the packing medium as properly part of the declared net weight, if the packing medium is generally consumed as part of the food. Where solid foods are packed in a salt brine or other medium which is considered inedible and almost always discarded before serving, declaration of drained weight of the food, instead of the net weight, has been recommended * * *" (Also see the December 9, 1977 **Federal Register**, 42 FR 62282, pertaining to drained and filled weight.)

FDA has adopted a tare weight sampling plan for standard-weight nonglass and nonaerosol containers, that is, those individual food packages whose net weights exist in one or more designated sizes, such as 6 oz, 18 oz, 2 lb, etc. The total number of tares for any lot sample size (10, 30, or 50 units) is determined by considering the range of three randomly selected package tares. The broader the tare weight range, which indicates increased tare weight variability, the greater the number of tare weight determinations that would be required. Should a given lot appear to be violative, FDA will determine tare weights for at least 6, 12, or 18 tares from samples numbering 10, 30, or 50 units, respectively.

FDA also proposes to adopt the approach for tare determinations for glass and aerosol packages presented in the draft of the revision of NBS Handbook 67, dated December 1977 and modified by memorandum in August 1978. This revised draft will soon be replaced by new NBS Handbook 133.

Because FDA inspections are usually performed in the plant or warehouse, FDA supports a production lot definition and therefore proposes to define a lot as a collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

As stated earlier, the proposed regulation provides for sample sizes of 10, 30, or 50 units, depending on the number of packages in the lot. As a practical matter, however, the FDA sampling practices will rarely result in a sample size of less than 50 because FDA ordinarily will weigh at production or storage sites where larger lot sizes are available. The proposal provides for small lot samplings in those instances where retail lots will be weighed, a relatively rare procedure for FDA but more common for State and local regulatory officials.

The sample size of 10 has been incorporated into the proposed regulation for lots containing 250 or fewer units as described in the National Bureau of Standards revised draft of Handbook 67. FDA is proposing to add the sample size of 50 for lots containing above 3,200 units to provide a sufficiently high sampling density for FDA compliance purposes.

For individual units within a sample, this proposal prescribes maximum allowable short weight variations (MAV) for specified ranges of labeled net weights. The MAV's range from 1 percent for labeled weights exceeding 54.40 pounds to 10 percent for some of the lower weight food packages. FDA has incorporated the proposed MAV's from the NBS revised draft of Handbook 67.

Two criteria must be met when assessing samples for compliance with respect to the net weight labeling regulations: unit net weight requirement and the sample average net weight requirement. The unit net weight requirement specifies that, when considering samples of 10 or 30 units, each unit must meet or exceed the labeled net weight less the combination of the MAV and, where appropriate, the specified moisture allowance (to be discussed shortly). When considering a sample of 50 units, no more than one unit may fail to meet or fail to exceed the labeled net weight less the combination of the MAV and, when appropriate, the specified moisture loss. The sample average net weight requirement establishes that the average net weight of the sample must meet or exceed the labeled net weight, allowing only for moisture loss when appropriate.

Because random weight food packages such as cheeses are often weighed and labeled individually in retail stores and because random-weight packages are stored and handled under more carefully controlled conditions, such packages are less likely to suffer weight deviations from either mechanical filling operations or moisture loss to the same extent as standard-weight packages containing the same product. Consequently, random-weight packages, that is, those individual food packages whose weights are not designated and may be highly variable, should be permitted less weight variation than the standard-weight counterparts. The modifications detailed below reflect these alterations.

Like standard weight packages, random-weight packages must satisfy two criteria, a sample average net weight requirement and a unit net weight requirement, for compliance with the net weight labeling regulations. In addition, tare weights must be determined individually for each random-weight package.

The sample average net weight requirement for random-weight packages establishes that the lot represented by the sample fails if the average net weight of the sample is less than the average of the declared net weights of the individual units in the sample after allowing for designated moisture losses that are specific for random-weight packages. The acceptable designated moisture losses for random-weight packages are established by considering specific moisture loss studies under comparable packaging, handling, and storage conditions. If the sample average net weight is equal to or greater than the average of the declared net weights of the units constituting the sample, that lot represented by the sample is in compliance with the net weight labeling regulations, provided that the following conditions are met. When considering samples of 10 or 30 units, each unit must meet or exceed the labeled net weight less the combination of the MAV as determined by the smallest-weight package contained in the sample and, when appropriate, a designated percentage of the moisture loss explicitly identified by FDA regulations

for those random-weight foods. To remain in compliance with the net weight labeling regulations when considering samples with 50 units, no more than one unit may fall outside the range as described above.

Categories of Foods Subject to Moisture Loss

This document proposes to provide maximum permitted levels of moisture loss for various food categories. In the process of establishing maximum permitted levels of moisture loss for these food classes, FDA considered studies on moisture content and moisture loss available in the literature, and pertinent written information provided to FDA during and shortly after the public hearings on net weight labeling. Consideration was also given to the moisture loss characteristics imparted by the specific packaging materials employed and the effects of average anticipated storage time for each food. FDA proposes to establish moisture loss allowances for certain foods on the basis of similarity with those foods for which data are available. While a variety of sources for moisture loss data were consulted, it should be emphasized that the moisture loss allowances actually proposed are based only on FDA studies.

Standard-weight packaged foods subject to moisture loss have been placed into one of three food categories identified by maximum allowable moisture loss: one category of not more than 1 percent, a second category of not more than 3 percent, and a third category of not more than 4 percent. Foods permitted up to 1 percent moisture loss include frozen fruits and frozen vegetables packaged in cartons. Soft-ripened cheese packaged in loose wrappers are permitted up to 3 percent moisture loss, and flour packaged in kraft paper bags in permitted up to 4 percent moisture loss. Random-weight packaged soft-ripened cheeses are permitted a maximum of 1 percent moisture loss. No moisture loss allowance is proposed for foods other than those foods identified above or those that may be identified by well-defined studies (see below) as legitimately exhibiting moisture loss when properly packaged, handled, and stored.

As noted previously, proposed moisture allowances were designated for certain foods by analogy to similar foods (similar under comparable conditions of processing, packaging, and storage) for which moisture loss data exist. Thus, for example, all frozen fruits and vegetables packaged in cartons would be allowed a 1 percent moisture loss, although data are available only for frozen vegetables.

The Food and Drug Administration has available a limited amount of moisture loss data that were developed under well-defined conditions (Ref. 1). The agency acknowledges that deficiences may exist and that refinements, revisions, and additions of foods to the proposed moisture loss categories may be in order. Additional moisture loss categories may be proposed if justified by submitted data. Other standard-weight and random-weight packaged foods susceptible to moisture loss but not identified in this document may be eligible for moisture loss allowances. Moisture loss studies of appropriate quantity and quality must be submitted to FDA for review before additional moisture loss allowances will be proposed. While other packaged foods such as dried fruits and macaroni and noodle products have been reported to lost moisture during storage, a reasonable judgment regarding an acceptable level of moisture loss could not be made for one of the following reasons: adequate data quantifying moisture loss were not provided to FDA, conditions for data acquisition were improper or ill-defined, or reported ranges of observed moisture loss were too broad to support a recommendation for a proposed level of moisture loss. Providing a sufficiently narrow range of moisture loss for a food under well-defined conditions enables a critical evaluation of the data to be made. This, in turn, enables a tolerance to be proposed that is intended to protect consumer interests while not creating undue hardships for manufacturers and packagers.

Neither consumer nor industry representatives identified unreasonably large deviations due to moisture gain as a problem. In addition, overfilling during packaging is self-limiting from an economic standpoint. Consequently, establishing maximum permitted deviations above the declared weight was not considered further.

During the comment period or thereafter, interested persons having pertinent data on moisture loss characteristics are encouraged to provide the information to FDA. Data describing moisture loss (or gain) under well-defined conditions (temperature, humidity, duration of storage, packaging materials, etc.), as well as a comparison with the most commonly encountered conditions in the retail stores, are specifically solicited. These submissions should be addressed to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

References

A copy of each of the following reference documents has been placed on file with the Hearing Clerk, Food and Drug Administration.

1. Internal FDA Memorandum entitled "Data for Proposed Net Weight Tolerances," February 13, 1979.

2. Internal FDA Memorandum entitled "Net Weight Sampling Plans," October 23, 1978.

3. Internal FDA Memorandum entitled "Net Weight Labeling—Proposed Regulation—Shrinkage Allowance for Random Weight Units of Soft-Ripened Cheese," August 21, 1979.

4. Draft of revised National Bureau of Standards Handbook 67, "Checking Prepackaged Commodities," December 1977 and memoranda updating the draft, August 1978.

The potential environmental effects of this action have been carefully considered, and the FDA has concluded that the action will not significantly affect the quality of the human environment. This action is one of a type for which the agency has determined that the preparation of an environmental impact statement is not required, except in rare and unusual circumstances (21 CFR 25.1(f)(12)). Accordingly, the preparation of an environmental impact analysis report for this action is not required pursuant to 21 CFR 25.1(g).

The agency proposes that the final regulation based on this proposal be made effective 90 days after the date the final regulation is published in the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 403, 701, 52 Stat. 1041 as amended, 1046–1048 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(n), 343, and 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 101, as follows:

1. In § 101.105 by revising paragraph (q), to read as follows:

§ 101.105 Declaration of net quantity of contents when exempt.

* * * * *

(q) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents in the package. The quantity of contents shall not be less than the statement of the quantity of contents on the package, except as permitted by § 101.106.

* * * * *

2. By adding new § 101.106 to Subpart F, to read as follows:

§ 101.106 Net weight: compliance determinations and reasonable variations from the labeled quantity.

(a) Compliance with the net weight requirements of § 101.105(q) shall be determined in accordance with the provisions of this paragraph.

(1) *Net weight requirements for standard-weight food packages.* The sample fails if it does not meet both the unit and the average net weight requirements of this paragraph.

(i) *Unit net weight requirement.* (*a*) When considering a sample consisting of 50 units, no more than one unit may weigh less than either the weight obtained by subtracting from the labeled net weight the applicable maximum allowable variation in paragraph (b) (Table 4) of this section, or, when a moisture allowance is permitted, the weight obtained by subtracting from the labeled net weight the combined total of the applicable allowable variation in paragraph (b) of this section and the allowance for moisture loss in paragraph (c) (2), (3), or (4) of this section, as appropriate.

(*b*) When considering a sample consisting of 10 or 30 units, no unit shall weigh less than the appropriate weight obtained in accordance with paragraph (a)(1)(i)(*a*) of this section.

(ii) *Sample average net weight requirement.* The sample average net weight (the average net weight of the units in the sample), analyzed according to the sampling plan in paragraph (a)(3) of this section, is equal to or greater than the labeled net weight. Except for foods listed in paragraph (c) (2), (3), and (4) of this section the average net weight of the units in the sample is equal to or greater than the labeled weight minus the allowance for moisture loss for that food as specified in paragraph (c) (2), (3), or (4) of this section, as appropriate.

(2) *Net weight requirements for random-weight food packages.* The sample fails if it does not meet both the unit and the average net weight requirements of this paragraph.

(i) *Unit net weight requirement.* (*a*) When considering a sample consisting of 50 units, no more than 1 unit may weigh less than either the weight obtained by subtracting from the labeled net weight the maximum allowable variation from paragraph (b) (Table 4) of this section as determined by the smallest weight package contained in the sample, or, when a moisture allowance is permitted, the weight obtained by subtracting from the labeled net weight the combined total of the applicable allowable variation in paragraph (b) (Table 4) of this section as determined by the smallest weight package contained in the sample and the allowance for moisture loss in paragraph (d) of this section.

(*b*) When considering a sample consisting of 10 or 30 units, no unit shall weigh less than the appropriate weight obtained in accordance with paragraph (a)(2)(i)(*a*) of this section.

(ii) *Sample average net weight requirement.* The sample average net weight (the average net weight of the units in the sample), analyzed according to the sampling plan in paragraph (a)(3) of this section, is equal to or greater than the average of the labeled net weights. Except for foods listed in paragraph (d) of this section, the average net weight of the units in the sample is equal to or greater than the labeled weight minus the allowance for moisture loss for that food as specified in paragraph (d) of this section.

(3) *Sampling plan.* (i) A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade constitutes a lot.

(ii) (*a*) The tare weight for nonfrozen food products shall be the weight of the package materials, including adhesives, labels, ties, etc., and the weight of any adhering or absorbed juices, fats, or solids that would normally not be consumed. Any large portions of food adhering to the package materials during the tare weight assessment are to be removed from the package in a manner consistent with usual consumer practices.

(*b*) The tare weight for frozen products shall be the weight of the container and any ice crystals adhering to the surface of the package materials.

(iii) The sample for determining the quantity of contents shall consist of 10, 30, or 50 units (primary containers of food) chosen at random from the lot. The number of units to be chosen depends on lot size and shall be determined in accordance with Table 1 of this paragraph.

Table 1.—*Sample Sizes for Determination of Compliance With Net Weight Declaration*

Lot size (primary containers)	Sample size (number of units or primary containers of food)
250 or less	10
251 to 3,200	30
3,201 or above	50

(iv) (*a*) The total number of tare weights for any standard weight lot sample described in this section is determined by considering the range of three randomly selected package tares in accordance with Table 2 of this paragraph.

Table 2.—*Number of Tare Weight Determinations Required for Assessment of Compliance With Net Weight Declaration*

Range of three tares (ounces or grams)	Minimum number of tares required
⅛ oz (3.54 g) or less	3
More than ⅛ oz (3.54 g) to and including $^{9}/_{16}$ oz (5.32 g)	6
More than $^{9}/_{16}$ oz (5.32 g) to and including ¼ oz (7.09 g)	9
More than ¼ oz (7.095 g) to and including $^{5}/_{16}$ oz (8.86 g)	[1] 12
More than $^{5}/_{16}$ oz (8.86 g)	[1] 15

[1] If only 10 units are to be sampled because the lot size was 250 units or less, all 10 tares shall be measured.

(*b*) If the lot appears to be violative, at least 6, 12, or 18 tare-weight determinations shall be required for samples numbering 10, 30, or 50 units, respectively.

(*c*) For glass or aerosol containers, the total number of tare weights to be obtained for lot samples of 10, 30, or 50 units shall be based on an initial tare sample of 6, 12, or 18 randomly chosen units, respectively; the numbers of tares shall be increased where necessary to reach the total number, as determined by the ratio of the range between the lowest and highest unit net weights (RC) and the range between the lowest and highest tare weights (RT). Based on the RC/RT ratio the total number of empty aerosol or glass containers to be used in determining the tare weight shall be in accordance with the sampling schedule in Table 3 of this paragraph.

Table 3.—*Total Number of Empty Aerosol or Glass Containers To Be Used In Determining the Tare Weight*

RC/RT ratio	Total number of empty aerosol or glass containers		
	Sample size: 10	Sample size: 30	Sample size: 50
0.2 or less	10	30	50
0.21 to 0.40	10	29	49
0.41 to 0.60	10	28	46
0.61 to 0.80	9	26	44
0.81 to 1.00	8	24	40
1.01 to 1.20	8	23	37
1.21 to 1.40	8	21	34
1.41 to 1.60	7	19	31
1.61 to 1.80	6	17	28
1.81 to 2.00	6	15	25
2.01 to 2.20	6	14	23
2.21 to 2.40	6	13	21
2.41 to 2.60	6	12	19
2.61 to 2.80	6	12	18

(*d*) Tare weights for each random weight package must be determined individually.

(b) *Maximum allowable variation applicable to units.* The maximum allowable variation below the labeled

net weight appears in Table 4 of this paragraph.

Table 4.—*Maximum Allowable Variation Below the Net Weight* [1]

Labeled net weight, pounds or ounces	Maximum allowable variation of the net weight	
	Decimal lb.	Fractional oz.
0.026 lb or less	0.001	
0.41 oz or less		
More than 0.026 lb to and including 0.04 lb	0.002	1/32
More than 0.41 oz to and including 0.64 oz		
More than 0.04 lb to and including 0.08 lb	0.004	1/16
More than 0.64 oz to and including 1.28 oz		
More than 0.08 lb to and including 0.12 lb	0.008	1/8
More than 1.28 oz to and including 1.92 oz		
More than 0.12 lb to and including 0.18 lb	0.012	3/16
More than 1.92 oz to and including 2.88 oz		
More than 0.18 lb to and including 0.26 lb	0.016	1/4
More than 2.88 oz to and including 4.16 oz		
More than 0.26 lb to and including 0.34 lb	0.020	5/16
More than 4.16 oz to and including 5.44 oz		
More than 0.34 lb to and including 0.46 lb	0.024	3/8
More than 5.44 oz to and including 7.36 oz		
More than 0.46 lb to and including 0.58 lb	0.028	7/16
More than 7.36 oz to and including 9.28 oz		
More than 0.58 lb to and including 0.70 lb	0.032	1/2
More than 9.28 oz to and including 11.20 oz		
More than 0.70 lb to and including 0.84 lb	0.036	9/16
More than 11.20 oz to and including 13.44 oz		
More than 0.84 lb to and including 0.94 lb	0.40	5/8
More than 13.44 oz to and including 15.04 oz		
More than 0.94 lb to and including 1.08 lb	0.044	1 11/16
More than 15.04 oz to and including 17.28 oz		
More than 1.08 lb to and including 1.26 lb	0.048	3/4
More than 1.26 lb to and including 1.40 lb	0.052	1 13/16
More than 1.40 lb to and including 1.54 lb	0.056	7/8
More than 1.54 lb to and including 1.70 lb	0.060	1 15/16
More than 1.70 lb to and including 1.88 lb	0.064	1
More than 1.88 lb to and including 2.14 lb	0.070	1 1/8
More than 2.14 lb to and including 2.48 lb	0.078	1 1/4
More than 2.48 lb to and including 2.76 lb	0.086	1 3/8
More than 2.76 lb to and including 3.20 lb	0.094	1 1/2
More than 3.20 lb to and including 3.90 lb	0.11	1 3/4
More than 3.90 lb to and including 4.70 lb	0.12	2
More than 4.70 lb to and including 5.80 lb	0.14	2 1/4
More than 5.80 lb to and including 6.80 lb	0.15	2 1/2
More than 6.80 lb to and including 7.90 lb	0.17	2 3/4
More than 7.90 lb to and including 9.40 lb	0.19	3
More than 9.40 lb to and including 11.70 lb	0.22	3 1/2
More than 11.70 lb to and including 14.30 lb	0.25	4
More than 14.30 lb to and including 17.70 lb	0.28	4 1/2
More than 17.70 lb to and including 23.20 lb	0.31	5
More than 23.20 lb to and including 31.60 lb	0.37	6
More than 31.60 lb to and including 42.40 lb	0.44	7
More than 42.40 lb to and including 54.40 lb	0.50	8
More than 54.40 lb		[2] 1

[1] For conversion into metric units the following conversion factors are provided:
1 lb equals 0.4536 kilogram.
1 ounce equals 28.35 grams.
[2] Percent.

(c) *Maximum allowances for moisture loss for standard-weight food packages.* Maximum allowances for moisture loss, expressed as a percentage of the labeled net weight, for specified foods with packaging materials identified are as follows:

(1) No allowance for moisture loss is permitted if:

(i) The food is not subject to moisture loss, or

(ii) The food is packaged in a hermetically sealed container, or

(iii) The average net weight of all of the Units of the sample, at the time of initial shipment in interstate commerce, is less than the declared weight.

(2) One percent for the following foods: Frozen fruits and frozen vegetables packaged in cartons.

(3) Three percent for the following foods: Cheeses, natural, soft-ripened (e.g., camembert and leiderkranz) packaged in loose wrappers.

(4) Four percent for the following foods: Flours packaged in kraft paper bags.

(d) *Maximum allowances for moisture loss for random-weight food packages.* Maximum allowances for moisture loss, expressed as a percentage of the labeled net weight, for specified foods are as follows: One percent for the Following foods; Cheeses, natural, soft-ripened, (e.g., Camembert and liederkranz).

Interested persons may, on or before November 6, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments. The comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: May 16, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

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